UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: BIOGEN INC. SECURITIES LITIGATION	)	**Civil Action No. 15-13189-FDS**

MEMORANDUM AND ORDER
ON DEFENDANTS' MOTION TO DISMISS

SAYLOR, J.

This is a putative class action involving alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a), and SEC Rule 10b-5. Lead plaintiff GBR Group, Ltd. has brought suit, on behalf of a class of similarly situated persons, against biopharmaceutical company Biogen Inc. and three Biogen executives. Plaintiffs contend that class members were harmed when they purchased Biogen's common stock at prices that were artificially inflated by the company's materially misleading statements and omissions about Tecfidera, its leading multiple sclerosis drug.

The complaint relies heavily on statements by ten former Biogen employees acting as confidential witnesses. It alleges that defendants, after publicly announcing in October 2014 that a patient being treated with Tecfidera had died, both withheld material information about declining Tecfidera sales and made misleading positive statements about future revenue. Plaintiffs assert that three Biogen executives made more than twenty materially false misrepresentations and omissions during various earnings calls and conferences between December 2, 2014, and July 23, 2015.

Defendants have moved to dismiss the complaint pursuant to Fed. R. Civ. P. 12(b)(6) and the Private Securities Litigation Reform Act of 1995, 15 U.S.C. §§ 78u-4, 78u-5.[1] Defendants contend that the complaint should be dismissed for two principal reasons. First, they contend that the complaint fails to set forth plausible allegations that the individual defendants' statements contain actionable misrepresentations or omissions. Specifically, defendants contend that the alleged misrepresentations are either (1) forward-looking statements protected by the PSLRA safe harbor provisions, (2) immaterial statements of corporate optimism or puffery, or (3) not adequately alleged to be false at the time they were made. Second, they contend that the complaint fails to allege specific facts that give rise to a strong inference of scienter.

As the First Circuit has recently stated, "[n]ot all claims of wrongdoing by a company make out a viable claim that the company has committed securities fraud." *Fire and Police Pension Ass'n of Colo. v. Abiomed, Inc.*, 778 F.3d 228, 231 (1st Cir. 2015). The complaint does not, for example, allege that Biogen's current or historical financials are misleading because of fictitious sales, off-label marketing, inventory parking, or any similar act of corporate fraud. Rather, it alleges in substance that Biogen executives made statements about future Tecfidera sales that were misleading because they were unduly optimistic.

Although most of the alleged misrepresentations appear to be non-actionable, after drawing all reasonable inferences on behalf of plaintiffs, the complaint alleges a plausible claim for at least one material misrepresentation or omission. However, the complaint's allegations that defendants acted with the requisite degree of scienter fail to clear the relatively high hurdle

[1] Defendants also base their motion to dismiss on Fed. R. Civ. P. 9(b). "Of course, plaintiffs alleging securities fraud must also meet the Rule 9(b) standard for pleading fraud with particularity." *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 58 (1st Cir. 2008). However, "[t]he PSLRA is consistent with [the First Circuit's] prior application of Federal Rule of Civil Procedure 9(b) to securities fraud actions, a standard which is 'notably strict and rigorous.'" *Id.* at 58 n.7 (quoting *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 193 (1st Cir. 1999)).

of the PSLRA. Even assuming that defendants made a materially false or misleading statement, plaintiffs have not sufficiently alleged that defendants made those statements with a "conscious intent to defraud or 'a high degree of recklessness.'" *ACA Fin.*, 512 F.3d at 58 (quoting *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 82 (1st Cir. 2002)). Instead, the most compelling inference that can be drawn from the complaint as a whole is that defendants were, at worst, negligent, or engaged in permissible puffery. But "negligence or puffing are not enough for scienter . . . ." *Automotive Indus. Pension Trust Fund v. Textron Inc.*, 682 F.3d 34, 39 (1st Cir. 2012). Accordingly, and for the reasons set forth below, defendants' motion to dismiss will be granted.

I. Factual Background

Unless otherwise noted, all facts are stated as set forth in the complaint.[2]

A. The Parties and Tecfidera

Lead plaintiff GBR Group, Ltd. is a limited partnership located in Jacksonville, Florida. (Compl. ¶ 30).[3] The complaint alleges that GBR purchased Biogen securities at artificially inflated prices during the class period, which is December 2, 2014 through July 23, 2015. (*Id.* ¶¶ 1, 30).

Biogen Inc. is based in Cambridge, Massachusetts. (*Id.* ¶ 32). It is a global biopharmaceutical company that develops, manufactures, and markets treatments for certain

[2] Defendants' motion to dismiss is accompanied by 29 exhibits, including SEC filings and transcripts of Biogen earnings calls and securities-research conferences. While ordinarily "any consideration of documents not attached to the complaint, or not expressly incorporated therein, is forbidden . . . courts have made narrow exceptions for documents the authenticity of which are not disputed by the parties; for official public records; for documents central to plaintiffs' claim; or for documents sufficiently referred to in the complaint." *Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1993). It has become standard for courts considering motions to dismiss in securities fraud cases governed by the PSLRA to consider financial statements and transcripts referred to in the complaint. *See, e.g.*, *Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 232 n.2. Accordingly, the Court will consider the submitted exhibits. In presenting defendants' allegedly fraudulent misrepresentations, bold text indicates language that is included in the complaint, with italicized text indicating emphasis added by plaintiffs in the complaint. All additional language from the exhibits is provided for contextual purposes.

[3] All citations are to the amended complaint.

neurological, autoimmune, and hematological diseases, including multiple sclerosis ("MS"). (*Id.* ¶ 43). Biogen's securities trade on the NASDAQ under the ticker "BIIB." (*Id.* ¶ 32).

The complaint alleges claims against Biogen and individual defendants George Scangos (the Chief Executive Officer), Paul Clancy (the Chief Financial Officer and Executive Vice President, Finance), and Stuart Kingsley (the former Executive Vice President, Global Commercial Operations). (*Id.* ¶¶ 33-35).

Tecfidera is one of Biogen's four principal drugs for the treatment of MS. (*Id.* ¶ 43). It is an oral pharmaceutical approved for use in the United States and European Union. (*Id.*).[4] Tecfidera competes with other oral MS drugs as well as injectable MS treatments. (*Id.* ¶ 2). After the FDA approved Tecfidera for use in March 2013, Biogen began selling it in the United States during the second quarter of 2013. (*Id.* ¶¶ 2, 43). In 2015, the wholesale cost of Tecfidera was approximately $70,000 per patient per year. (*Id.* ¶ 43).

The complaint alleges that Tecfidera's revenue growth was a function of three factors: (1) the portion of new starts that Tecfidera captured (that is, patients recently diagnosed with MS and starting their treatment with Tecfidera); (2) patients switching over to Tecfidera from other drugs (referred to as "switches" or the "switch rate"); and (3) the growth of the overall market for oral MS drugs. (*Id.* ¶ 6). Conversely, Tecfidera revenue could be negatively affected by declining overall market growth, lower new starts, and a higher "discontinuation rate"—that is, "the rate at which patients were taken off the drug." (*Id.* ¶ 8).[5]

From its 2013 launch, Tecfidera was a significant source of revenue for Biogen, and it

[4] According to a recent Form 8-K, Biogen now appears to develop and market five MS drugs. (Def. Ex. 25 at 17).

[5] The discontinuation rate captures Tecfidera patients who pass away, choose to end MS treatment altogether, or switch to another treatment option offered by Biogen or its competitors.

fueled much of the company's growth. In 2015, Tecfidera was Biogen's highest grossing product by more than $1 billion in revenue. (Def. Ex. 25 at 17). Defendants publicly acknowledged Tecfidera's importance to the company. In Biogen's quarterly reports and annual report released during the class period, the company stated that it "may be substantially dependent on sales from our principal products for many years, including an increasing reliance on sales of Tecfidera as we expand into additional markets." (Compl. ¶ 45). In January 2015, when Biogen issued fiscal guidance for the year, the company stated that its "plan assumes Tecfidera will represent the largest contributor to our overall revenue growth." (*Id.*). The following charts display quarterly and annual revenue for Tecfidera individually and for Biogen as a whole, as well as revenue growth rates. (*Id.* ¶ 43).[6]

Quarterly Revenue

Quarter	Tecfidera Revenue ($MM)	Tecfidera Revenue QoQ Growth Rate	Biogen Revenue ($MM)	Biogen Revenue QoQ Growth Rate	Tecfidera Revenue % Biogen Revenue
2Q 2013	$ 192	-	$ 1,723	-	11.1%
3Q 2013	$ 286	49.1%	$ 1,828	6.1%	15.7%
4Q 2013	$ 398	39.0%	$ 1,966	7.6%	20.2%
1Q 2014	$ 506	27.1%	$ 2,130	8.3%	23.7%
2Q 2014	$ 700	38.5%	$ 2,421	13.7%	28.9%
3Q 2014	$ 787	12.4%	$ 2,511	3.7%	31.3%
4Q 2014	$ 916	16.4%	$ 2,641	5.1%	34.7%
1Q 2015	$ 825	(9.9%)	$ 2,555	(3.2%)	32.3%
2Q 2015	$ 883	7.1%	$ 2,592	1.4%	34.1%
3Q 2015	$ 937	6.1%	$ 2,778	7.2%	33.7%
4Q 2015	$ 993	5.9%	$ 2,839	2.2%	35.0%

[6] The complaint includes Biogen and Tecfidera revenue through the second quarter of 2015. For completeness, revenue for Biogen and Tecfidera is provided from the company's SEC filings on an annual basis, as well as on a quarterly basis through the fourth quarter of 2015. (Def. Exs. 1, 11, 24, 25).

Annual Revenue						
Year	Tecfidera Revenue ($MM)	Tecfidera Revenue YoY Growth Rate	Biogen Revenue ($MM)	Biogen Revenue YoY Growth Rate	Tecfidera Revenue % Biogen Revenue
2013	$ 877	-	$ 6,932	-	12.6%
2014	$ 2,909	231.9%	$ 9,703	40.0%	30.0%
2015	$ 3,638	25.1%	$ 10,764	10.9%	33.8%

B. The PML Death and its Impact on Tecfidera Sales

1. The PML Death

On October 22, 2014, Biogen released its third-quarter financial results, announcing revenues of $2.51 billion, up 3.7 percent from the previous quarter. (*Id.* ¶ 48). It also announced third-quarter revenue for Tecfidera of $787.1 million, which was a 12.4 percent increase from the previous quarter. (*Id.*). However, Tecfidera's growth rate had decreased significantly from the growth rates of 49.1, 39.0, 27.1, and 38.5 percent in the previous four quarters. (*Id.* ¶ 43).

During its earnings call, Biogen publicly announced, for the first time, that an MS patient who had taken Tecfidera for more than four years as part of a clinical study had died of progressive multifocal leukoencephalopathy ("PML"). (*Id.* ¶ 48). PML is an infection that is particularly dangerous for individuals with a weakened immune system. (*Id.* ¶¶ 4, 48).[7] During that earnings call, CEO Scangos stated:

> We would like to inform you that we have confirmed a case of PML in a patient being treated from Tecfidera who recently died from complications of pneumonia. Despite this tragic loss, we believe the overall positive benefit risk profile of Tecfidera remains unchanged.
>
> The patient was treated with Tecfidera for four and a half years as part of the ENDORSE study. During the course of therapy, the patient experienced severe lymphopenia that lasted for over three and a half years. Lymphopenia is a known risk factor for PML and can be caused by a number of factors, including treatment for MS, cancer, [and] HIV.
>
> The current Tecfidera label includes warnings and precautions regarding lymphopenia. We **reported the case to the regulatory authorities and will work with them to confirm that the language on our label provides**

[7] The complaint does not allege that Biogen failed to announce the PML death promptly.

patients and their physicians appropriate information regarding lymphopenia.

(*Id.* ¶ 48; Def. Ex. 7 at 3).[8]

When the call was opened to questions from research analysts, the first question focused on Tecfidera's future growth rate:

> Question: [O]n Tecfidera, looks like the growth on a quarter on quarter basis either absolute dollars or percentage basis, it looks a little bit lower in Q3 than, say, over any of the last four or five prior quarters. Was there anything one time nature that you want to call out? Or should we just assume that drug is on a different trajectory?
>
> Kingsley: Nothing big on a one time nature. Inventories are moderating, I think a little bit in the channel. As always a little probably difficult to predict exactly, but look, we have always expected Tecfidera's growth rate would moderate over time. I think we are seeing a natural case of that. But ***we are very comfortable with the trajectory of the product right now***. **We're very comfortable as we talked about the portion of new starts and switches we are getting. Nothing significantly off plan from our standpoint. I think we feel pretty good about the performance.**

(Compl. ¶ 48; Def. Ex. 7 at 7-8).

When asked a similar question about Tecfidera's overall growth prospects moving forward, Clancy responded that "we will use the end of the year call to give our expectations going into 2015," but then stated, among other things, "[w]e think **there is meaningful, still meaningful growth in Tecfidera in the United States, as we continue to penetrate doc[tors] and penetrate the marketplace**." (Compl. ¶ 49; Def. Ex. 7 at 9). Analysts continued to question defendants about Tecfidera's future growth in the United States:

> Question: [J]ust wanted to follow-up on the questions on Tecfidera in the US. You have gotten fairly rapidly to 20%, roughly 20% market share. Just wanted maybe your thoughts on how we should think about growth going forward.

[8] In its recitation of the facts, the Court will provide as much context as is necessary, sometimes including analysts' questions. As will become clear, the key inquiry in ruling on defendants' motion is whether the complaint, taken as a whole, pleads a strong inference of scienter—that is, an inference that the defendants either had a conscious intent to defraud or were highly reckless. The inference of scienter, a more demanding standard than mere negligence, must be at least as strong as any other inference of non-fraudulent intent. Accordingly, the context of defendants' statements is important to the key inquiry in ruling on defendants' motion.

Factors we should consider when modeling our sales going forward?

Kingsley: So look, the way to think about Tecfidera growth is what portion of new starts does Tecfidera capture?

We believe Tecfidera is capturing a nice portion of new starts and should. Physicians are comfortable putting new patients on it.

And then the bigger question, mathematically is what portion of switches. And again we believe the product is capturing a meaningful portion of switches.

There is a third factor, which is market growth. We have said, in some prior calls, that the market in the US has grown faster this year than it has, historically. Some of it is what Paul talked about before, which was the switch from free to commercial patients.

There is also the dynamic of the quitter pool, we think has been favorable this year. Essentially, Tecfidera has probably kept people in the markets who might have quit the market. So you have had additional growth on that standpoint.

You also have to look at how the market growth will moderate over time as you get to the more impact of unemployment rate of affordable care and some of the change of the balance in the switcher pool. We believe we are capturing what we believe is a very attractive portion of new starts and switches, and that is where we focus our effort.

(Def. Ex. 7 at 13-14).

Finally, one analyst focused on the potential implications of the PML death:

Question: I just want to better understand the potential implications, if any, from the case of PML.

We recognized there is a background rate of PML, in lymphopenic patients including those with multiple sclerosis. We know Tecfidera does lower lymphocyte count.

Do you think in light of what's happened here, would you prefer severely lymphopenic patients not be on Tecfidera? Do you expect that doc[tors] will reconsider use in lymphopenic patients?

And lastly, do you expect the regulators will update the label? Or will they wait for additional cases since there is a background rate in this population?

Scangos: Look, we are certainly **not in a position to make medical recommendations**, right? Lymphopenia, especially prolonged lymphopenia like

> the patient experienced is a known risk factor for PML.
>
> Tecfidera does result in lymphopenia in a small fraction of the patients who take it. It is for that reason that lymphocyte screening is on the label.
>
> We have reported this to the regulatory authorities. We certainly will be discussing with them whether the language on the label is appropriate to inform patients and physicians, and what is done with the lymphocyte results is I think up to the physician that is caring for those patients.

(Compl. ¶ 49; Def. Ex. 14-15).

According to the complaint, "[a]nalysts accepted defendants' statements that the PML death would not have a material impact on Tecfidera." (Compl. ¶ 50). One analyst concluded his October 22 report by stating "BOTTOM LINE: We see minimal commercial impact and believe shares are overreacting to the PML report." (*Id.* ¶ 53).

A month later, on November 25, 2014, the FDA issued a warning to the public about the patient who died from PML while using Tecfidera. (*Id.* ¶ 54). The FDA stated that the patient was not taking any other drugs associated with PML, and it advised physicians and patients to monitor Tecfidera patients for side effects. (*Id.*). It further noted that "[a]s a result, information describing this case of PML . . . is being added to the Tecfidera label." (*Id.*). Tecfidera's label was updated in the United States to include the PML risk on December 3, 2014, one day after the class period began. (Def. Ex. 9 § 5.2).

2. <u>Confidential Witness Allegations</u>

The complaint essentially alleges that defendants, shortly after announcing the PML death in October 2014, knew from both internal data and discussions with physicians that the PML incident was materially affecting Tecfidera sales—an effect that their public statements fraudulently or recklessly misrepresented and concealed. (*See* Compl. ¶¶ 56-75). In support of its allegations, the complaint relies heavily on statements from ten confidential witnesses

("CWs") who were formerly employed by Biogen across the country.[9] Many of the confidential witnesses were Biogen Area Business Managers ("ABMs"), defined by Biogen as a "specialty sales representative position [that is] called upon to sell our [n]eurology products [including Tecfidera] with key stakeholders in the [MS] community: including [n]eurologists, allied health professionals, and local MS chapters." (*Id.* ¶ 56 n.1).

CW1 was a Biogen ABM responsible for parts of southern Florida and Puerto Rico from November 2010 to June 2015. (*Id.* ¶ 56). He was five reporting levels removed from Scangos. (*Id.*). According to CW1, Tecfidera sales in his region "dropped steeply and immediately" after the announcement of the PML incident, and there was a "large drop" in new prescription sales of Tecfidera beginning around November 2014 for "almost all of the neurologist customers in his sales territory." (*Id.*). He stated that during a "late 2014" regional conference call, his supervisor, Regional Director Robert Nelson, told ABMs that their region was "not the only region where Tecfidera sales were poor; according to Nelson sales were down in almost every region across the United States." (*Id.*).

CW2 was a Biogen Market Research Manager from 2005 to December 2014. (*Id.* ¶ 57). He reported to Antonio Melo, Biogen's Senior Manager of Business Planning.[10] In November 2014, CW2 attended a Biogen "town hall" meeting led by CEO Scangos. (*Id.*). "According to CW2, Scangos's presentation (which included a visual component that reflected his talking

[9] Under the PSLRA, a plaintiff may rely on a confidential witness and need not provide his or her name as long as the witness is "described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 51 (1st Cir. 2008) (internal quotation marks omitted). Courts must evaluate confidential witnesses based on factors such as "the level of detail provided by the confidential sources, the corroborative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations, the number of sources, the reliability of the sources, and similar indicia." *Id.* (internal quotation marks omitted).

[10] It is unclear from the complaint where Melo and CW2 worked or where they were located on the company's organizational hierarchy compared to the individual defendants.

points) stated that 'the overall sense of the trajectory [at Biogen] was changing' following the Tecfidera PML death." (*Id.*). CW2 stated that the town hall meeting also included "a presentation on potential organizational changes as a result of the PML death." (*Id.*). According to the complaint, "[i]t was CW2's understanding that the organizational changes stemmed from executive management's expectation that the PML death would have 'an impact on performance.'" (*Id.*).

CW3 was a Biogen ABM responsible for parts of southern Florida and Puerto Rico from May 2012 to June 2015. (*Id.* ¶ 58). CW3 stated that "his Tecfidera sales were strong" until late 2014 or early 2015, when sales "dropped dramatically and failed to recover" by the time he left the company. (*Id.*). CW3 confirmed that there was a "large drop" in new Tecfidera prescription sales beginning around November 2014 for "almost all" of the neurologist customers in his territory. (*Id.*). According to the complaint, "[b]ased on conversations with his neurologist customers, CW3 attributed the decline in sales to the PML death and the subsequent FDA label change in November 2014." (*Id.*). CW3 stated that ABMs in "other Biogen regions" conveyed to him that their Tecfidera sales had also "decreased dramatically" by January 2015. (*Id.*). Around March 2015, CW3 attended a national sales meeting in Texas where an unnamed person described the PML incident as a "market event," and stated that Tecfidera sales were "not on track." (*Id.* ¶ 59). "According to CW3, [unnamed] speakers at the meeting stated that sales would need to pick up again if [Biogen] was going to meet [its] expected 14 [to] 16 percent revenue growth." (*Id.*).

CW1 also recalled a national meeting in Texas in March 2015. (*Id.* ¶ 60). According to CW1, "senior Biogen leaders" at the meeting "acknowledged" that the PML incident "definitely was impacting Tecfidera sales." (*Id.*). CW1 also stated that during a Tecfidera "town hall"

meeting led by three more senior Biogen employees, "metrics and graphs were presented that showed a sharp decline in Tecfidera sales in most regions." (*Id.*). According to CW1, one presenter stated that "we understand that the market event has had an impact on sales." (*Id.*).

CW4 was a Biogen ABM responsible for parts of Kansas and northern Oklahoma from March 2006 to June 2015. (*Id.* ¶ 61). CW4 reported to the regional director for the midwest region, who reported to the national sales director. (*Id.*). "CW4 stated that his Tecfidera sales dropped appreciably very early in 2015, while sales of other MS drugs continued to do very well." (*Id.*). According to CW4, "new prescription rates dropped, and physicians were transferring patients off Tecfidera and onto different therapies." (*Id.*). He received quarterly sales goals from Biogen's corporate office, but he did not meet his Tecfidera sales goals in 2015. (*Id.*). CW4 participated in biweekly conference calls with other regional ABMs in 2015; according to him, other "midwest region ABMs reported that they were not meeting their Tecfidera sales goals, up until the time of CW4's departure in June 2015." (*Id.*).

CW5 was a Biogen ABM responsible for parts of North Carolina and Virginia from April 2013 to April 2015. (*Id.* ¶ 62). According to CW5, Tecfidera was his "lead product" by early 2014, but he recalled a "big slowdown" in Tecfidera "market expansion" beginning in late October 2014, a slowdown that he discussed with other Biogen ABMs. (*Id.*). CW5 stated that "there was a linkage between the PML death and the drop in Tecfidera sales." (*Id.*). He also stated that other south region ABMs discussed on conference calls how "poorly" their Tecfidera sales were doing throughout the first quarter of 2015. (*Id.* ¶ 63). "CW5 also began to experience a serious downturn in 'start forms' for Tecfidera at the end [of the first quarter], from 10 to 14 per week to 3 per week around March 2015." (*Id.*).

CW6 was a Biogen ABM responsible for Montana, Idaho, and Wyoming from April

2011 to August 2015. (*Id.* ¶ 64). CW6 reported to a regional sales manager, who reported to a senior sales director. (*Id.*). "CW6 stated that prior to the October 2014 announcement of the PML death, Tecfidera had a 'hockey stick' (i.e., exponential) growth." (*Id.*). CW6 stated that following the October 2014 announcement, his Tecfidera new starts "declined" by the end of 2014, and that his new Tecfidera prescriptions then "significantly slowed down." (*Id.*). According to CW6, people were "more cautious" following the PML death. (*Id.*).[11] He learned during conference calls that the "decline or stoppage" in new Tecfidera patients following the PML death also occurred in other regions. (*Id.*). According to him, Tecfidera sales never rebounded in 2015 before his departure in August 2015. (*Id.*).

CW7 was a Biogen ABM responsible for parts of Virginia, West Virginia, and Maryland from April 2011 to June 2015. (*Id.* ¶ 65). CW7 reported to a regional sales manager, who reported to a senior sales director. (*Id.*). According to the complaint, "CW7 stated that his Tecfidera sales were consistently good prior to the announcement of the PML death in October 2014, but that after the PML announcement his territory 'took a hit' beginning in December 2014 or January 2015." (*Id.*).

CW8 was the senior director of commercial operations for Biogen, a position "equivalent to chief of staff for the head of commercial operations," from August 2014 to November 2015. (*Id.* ¶ 66). CW8 reported to the senior vice president of "U.S. commercial." (*Id.*). His responsibilities included oversight of operations related to Biogen's MS and hemophilia drugs, including Tecfidera, and he handled operational issues related to Tecfidera on a daily basis. (*Id.*). According to the complaint, "CW8 stated that all of 2015 was 'difficult' for Tecfidera and

[11] It is unclear whether those people were doctors, patients, or Biogen employees.

that beginning with the 'event in October,' he could not recall a time when Tecfidera's sales prospects were not a concern." (*Id.*).

CW9 was a Biogen ABM responsible for parts of Connecticut and New York from July 2009 to March 2015. (*Id.* ¶ 67). He reported to a regional director of sales, who reported to a national sales director, who reported to a vice president, who reported to the senior vice president of U.S. commercial. (*Id.*). According to the complaint, "CW9 observed that the ABMs in his territory were not compensated for their Tecfidera sales in [the first quarter of 2015], i.e., they did not meet their Tecfidera sales for that quarter." (*Id.*).

From July 2012 to October 2015, CW10 was an executive assistant in Biogen's "program leadership and management team," supporting numerous programs including Tecfidera. (*Id.* ¶ 68). CW10's responsibilities included supporting the Tecfidera program executive and program director, initially Alpna Seth, who was then replaced by Uthra Sundaram before the PML announcement. (*Id.*). According to the complaint, "Sundaram was a 'dotted line' report to Scangos." (*Id.*). According to CW10, Sundaram met weekly with CEO Scangos and Executive Vice President of Commercial Operations Kingsley, and quarterly with CFO Clancy. (*Id.* ¶ 69). "CW10 stated that after the PML death, Biogen's sales and commercial teams monitored sales numbers through various reports." (*Id.*). According to CW10, Biogen "immediately reached out to the top prescribing doctors as well as big pharmaceutical companies such as CVS Caremark and Walgreens after the PML announcement." (*Id.*). CW10 stated that Biogen's commercial team performed "deep drill downs" into sales numbers, including "reviews of specific territories that were lagging," and that Sundaram went on "ride-alongs" with Biogen's medical-science liaisons to meet with doctors and "discuss the PML death." (*Id.*). According to CW10, the "entire Tecfidera team" would meet during weekly program team meetings to discuss sales

numbers and how the PML death affected sales. (*Id.* ¶ 70). CW10 stated that Sundaram "communicated with Scangos and other senior executives following those meetings." (*Id.*). CW10 further stated that "Sundaram was involved in the Tecfidera label change after the PML death and knew that the label change would immediately lead to lost sales." (*Id.*).

According to the complaint, CW1 had access to his region's sales information, including the number of prescriptions written. (*Id.* ¶ 71). According to CW1, his regional director would access the sales metrics of other regions to compare their region's performance. (*Id.*). CW4 stated that the "company tracked sales metrics and prescriptions" and that "when a prescription was sold, Biogen's headquarters knew about it." (*Id.* ¶ 72). CW7 stated that "corporate headquarters would have had up-to-date insight into new prescription rates" because "forms needed to be filled out for every new Tecfidera prescription" and "corporate offices were given copies of th[o]se forms." (*Id.* ¶ 73). According to CW7, his territory's sales reports were updated nightly and included the identification number assigned to every new patient and the name of the prescribing neurologist. (*Id.*).

According to CW1, sales goals for Tecfidera "were adjusted downward" in December 2014 to make it easier for ABMs to reach compensation goals. (*Id.* ¶ 74). CW1 stated that many ABMs in his region still failed to meet the lowered goals. (*Id.*). CW5 stated that Biogen lowered Tecfidera sales goals around the same time. (*Id.* ¶ 75). According to him, a Biogen vice president sent an e-mail to ABMs in January 2015 announcing that compensation thresholds for sales representatives were being lowered because of "lower guidance due to unforeseen market events." (*Id.*). According to the complaint, CW5 understood the market events to be "based on problems with Tecfidera sales." (*Id.*).

C. Overview of the Class Period Timeline

The complaint alleges that "[f]ollowing the announcement of the PML death and the FDA's advisory, and contrary to the material decrease in sales reported internally by sales personnel across all regions, defendants publicly dismissed concerns that the PML death would materially impact Tecfidera performance . . . . [and] reassured investors that Tecfidera would continue to drive double-digit revenues for Biogen in 2015." (*Id.* ¶ 76).

On October 22, 2014, before the start of the class period, Biogen released third quarter 2014 financial results and announced the PML incident. (*Id.* ¶¶ 48-49). CFO Clancy and Doug Williams (Biogen's executive vice president of research and development) spoke on an investor conference call on December 2, 2014. (*See id.* ¶¶ 106-08). CEO Scangos spoke during a healthcare conference on January 12, 2015. (*See id.* ¶¶ 108-10).

On January 29, 2015, Biogen announced fourth-quarter results, reporting Tecfidera revenues of $916 million, up 16.4 percent from the third quarter, which was 34.7 percent of total Biogen revenue. (*Id.* ¶ 77). As part of its practice to issue projected revenue guidance twice per year, defendants projected annual Biogen revenue growth of 14 percent to 16 percent for 2015. (*Id.*). Biogen's stock rose 0.6 percent on January 29, 2015, and 10.2 percent the next day. (*Id.* ¶ 77 n.3). Scangos, Clancy, and Kingsley all spoke during the earnings call. (*See id.* ¶¶ 111-19). Analysts reacted positively to Biogen's fourth-quarter earnings and defendants' statements during the call. (*See id.* ¶¶ 121-27).

After fourth-quarter earnings, Kingsley spoke during a February 25, 2015 healthcare conference. (*See id.* ¶¶ 128-30). Scangos also spoke during a March 2, 2015 healthcare conference. (*See id.* ¶¶ 131-32).

On April 24, 2015, Biogen released disappointing first-quarter earnings, announcing

Tecfidera revenue of $825 million, which was below the market's consensus estimates and a 9.9 percent decrease from the previous quarter. (*Id.* ¶ 85). On a company level, Biogen's total revenue decreased 3.2 percent from the previous quarter. (*Id.* ¶ 43). The complaint alleges that the earnings call on April 24 was the "first time [that] defendants partially acknowledged that the PML death was impacting Tecfidera sales." (*Id.* ¶ 85). In response, Biogen's stock price decreased 6.6 percent on April 24. (*Id.*). However, maintaining their practice of providing revenue guidance only twice per year, defendants did not change the projected annual revenue growth for Biogen of 14 to 16 percent that they had released after announcing fourth-quarter results in January. (*Id.* ¶ 86). Instead, Clancy stated, "If [Tecfidera's] U.S. trajectory does not improve, we may come in at the lower end of our previously provided [annual] revenue growth." (*Id.* ¶ 135).

After announcing first-quarter earnings, Clancy spoke during a healthcare conference on May 6, 2015. (*See id.* ¶¶ 139-40). A week later, Williams, not a named defendant in this action, spoke during a May 13 healthcare conference. (*See id.* ¶¶ 141-42). A week later, Kingsley spoke during a May 19 healthcare conference. (*See id.* ¶¶ 143-44). A week later, Clancy spoke during a May 27 strategic decisions conference. (*See id.* ¶¶ 145-47). On May 27, 2015, Biogen's stock price increased 2.5 percent, closing at $402.92. (*Id.* ¶¶ 93, 147).

On July 24, 2015, the day after the end of the class period, Biogen released second-quarter earnings. It announced Tecfidera revenue of $883 million, a 7.1 increase from the first quarter, but still less than the $916 million in revenue earned during the fourth quarter of 2014. (*Id.* ¶ 43). Biogen's total revenue increased 1.4 percent from the first quarter. (*Id.*).

Biogen revised its full-year 2015 revenue guidance, stating that "[r]evenue growth is expected to be approximately 6 percent to 8 percent compared to 2014 [down from the January

estimate of 14 percent to 16 percent], a decrease from prior guidance based largely on revised expectations for the growth of Tecfidera. Our balance of year forecast assumes limited patient growth for Tecfidera in the United States." (*Id.* ¶ 94; Def. Ex. 23 at 6).

During the earnings call, Scangos stated:

> **We had expected to see a reacceleration of Tecfidera, but that did not happen to any appreciable extent.** Rather Tecfidera experienced modest sequential patient growth, as we continued to work through the same commercial challenges experienced in the first quarter. We continue to believe that Tecfidera remains the preferred oral option in the MS market, based on its strong efficacy and favorable safety profile, and we're working hard across the organization to improve Tecfidera's trajectory.

(Compl. ¶ 150; Def. Ex. 23 at 3).

Kingsley stated:

> In light of continued headwinds affecting Tecfidera, we saw moderated patient growth for our MS portfolio as a whole this quarter.
>
> Our 2015 business plan for Tecfidera made two important assumptions: First, that Tecfidera would continue to stimulate higher than historical market growth and switch rates, as it drives the market from injectables to orals. And second, that Tecfidera, with what we believe is a strong all-in profile, would continue to capture a high rate of both new starts and switches. Through the second quarter, both of these were weaker than planned, particularly in the more mature and larger markets in the US and Germany.
>
> In the US, total market growth and switch rates remained lower than our original expectations, and appear to have returned to historical averages typically seen in the market before the launch of Tecfidera. **We believe the safety event reported in late 2014 has created greater caution on the part of both physicians and patients about switching to orals. Our US market research indicates a moderation in physician intent to prescribe, though in Q2, Tecfidera continued to gain patients in the US.**

(Compl. ¶ 150; Def. Ex. 23 at 5).

During the call, Kingsley responded to a question by stating, in part, "[l]ook, the first PML case was a pretty **significant change statement for the profile of Tecfidera, given its very pristine safety profile at the time.**" (Compl. ¶ 152; Def. Ex. 23 at 10). An analyst asked

"when you thought about Tecfidera and flat sales, how much—to what extent do you think there will be people stopping [the] drug versus just minimal growth?" Williams responded:

> Certainly one of the dynamics that we've seen, that we didn't expect was a **modest but not trivial increase in discontinuations in Tec[fidera] in the United States** in particular. That[] probably, we think, traces back to the monitoring to some extent. It traces back to efficacy breakthroughs, which is typical for most of the disease modifying or majority traces to [] some of the GI. So that is, both dynamics are actually happening. We're hopeful that we can actually bring that back to a bit normal state, but TBD, as we move forward.

(Compl. ¶ 153; Def. Ex. 23 at 13).

The market and analysts reacted negatively (Compl. ¶¶ 151-58), and Biogen's stock price decreased $85, or 22 percent, on July 24. (*Id.* ¶¶ 96, 154). The 22 percent decline occurred on unusually heavy trading volume, with 16.6 million shares traded compared with an average daily trading volume over the class period of 1.8 million shares. (*Id.* ¶ 154).

After the class period, during a September 18, 2015 healthcare conference, Kingsley stated "**[i]t was clear to us that we were going to get a—some kind of a downtick in the safety profile that *would have some kind of an impact on physician behavior*, but we couldn't tell.**" (*Id.* ¶ 98). He added that "**the [Tecfidera] label was so clean [before the PML incident], the first PML event was a pretty big change statement for a broad base of physicians who were very comfortable with having essentially no safety issues**." (*Id.*).

On October 9, 2015, Biogen announced that Kingsley was leaving the company. (*Id.* ¶ 99). Twelve days later, the company announced that it would eliminate approximately 11 percent of its workforce. (*Id.* ¶ 101).

D. Defendants' Statements During the Class Period

Below are the alleged materially false misrepresentations and omissions that defendants made during the class period. They occurred on ten dates between December 2, 2014, and May

27, 2015. Again, bolded text indicates the portion of the statements pleaded in the complaint, and italicized text indicates the specific portions of the statements that plaintiffs allege is actionable. All other text is provided for context.

1. December 2, 2014—Clancy on Analyst Call

The complaint alleges that Clancy made the following false and misleading statements about Tecfidera's "market share and discontinuation rates" during a conference call on the first day of the class period, December 2, 2014.

> Question: As you mentioned on the third-quarter call, [Tecfidera], it's capturing– –**Tecfidera is capturing around a third of new patients and 40% of the switch market. Do you think at this point Tecfidera is settling nicely at 35% market share in the overall market? Or where do you see Tecfidera going?**
>
> Clancy: Yes, usually your share of new starts in a market like [MS] ends up being a leading indicator of where you settle in. I think kind of jumping to that right now is a little bit of a stretch.
>
> . . . .
>
> **We still feel the market, broadly speaking, is moving to orals and *the indicators that we have is that Tecfidera is unquestionably the leading oral*.** Where this settles out kind of on a U.S. basis, on a world-wide basis is a TBD, but ***we think there's plenty of tailwind still left*.**
>
> Question: A question about like first-line. Given [Tecfidera] is more effective, theoretically you could be on this drug longer than, say, a first-line Avonex treatment. Do you have any sense—and it's not been long enough, but do you have any sense of how this is going to change duration of the first-line therapy versus, say, an Avonex in the first line?
>
> Clancy: The initial launch it didn't get—in the United States, it didn't get first-line. What we saw, which we always thought we would see, is some stickiness in the interferons and Copaxone as well. That is obviously changing the deeper we get into launch.
>
> So I think theoretically, yes, we could see that. Discontinuation rates, which people want to kind of be mindful of are tracking in the teens as well, so that is very consistent. We had always hoped that [those] would be a little bit lower, just being an oral therapy. There is not flu-like symptoms.

> But Tecfidera has the GI, as people know, and patients do obviously break through all therapies at some point in their disease progression. We hope that Tecfidera—we can get better performance in the discontinuation rates over a longer period of time. All those factors can help.
>
> Question: How soon do you think you could bring those down or what is the salesforce doing to lower the discontinuation rate and [educate] . . . ?
>
> Clancy: It's more than the salesforce. I think it's actually the patient service model that we have and have had for a long period of time. I think it is the product profile that inherently is more favorable, just from a relapse rate reduction. So from an efficacy perspective, oral is obviously easier and tolerated from a patient perspective.
>
> . . . .
>
> Question: Okay. Everyone asks me still, even though you've commented on this before, about the PML case and whether or not there will be a label change. Any updated thoughts? Any conversations with the FDA; updated thoughts about that?
>
> Clancy: We are obviously in conversations with the FDA. We expect a label change. The details of that—we have some visibility of that, but we can't really talk about that. It just actually wouldn't be—whatever we would say would end up being slightly different by the time we get it.
>
> I think the timing on it is hard to tell. I think . . . it leans closer to nearer in than a long time away. So, yes, we will just have to see when that comes. And that will—most of what I just said was related to the United States. Other parts of the world either have it in the label or will kind of update it as they see fit.

(Compl. ¶ 106; Def. Ex. 8 at 2-4).

The complaint alleges that Clancy's statements that "the indicators that we have is that Tecfidera is unquestionably the leading oral" and that he believed there was "plenty of tailwind still left" were false and misleading because he "knew there had been a 'big slowdown' in Tecfidera market expansion by November 2014 and that sales were down in almost every region in the United States." (Compl. ¶ 107).

2. January 12, 2015—Scangos at Conference

The complaint alleges that Scangos made the following false and misleading statements

about Tecfidera's "ability to drive business" during a healthcare conference on January 12, 2015.

> Scangos: ***So, 2014 was a really good year for Biogen [] and we believe that this can be sustained going into the future. Our core business based on our existing suite of products is robust, products continue to do well.*** The products that we launched recently will continue to be major drivers and will play an increasingly large part in our pipeline obviously as we go forward. ***We believe that [Tecfidera] will continue to be a major business driver*** **as it continues to expand in markets where it's already been introduced and as we introduce it into additional markets around the world**. And we believe that the mid and late stage programs are delivering and we have a very exciting early stage pipeline so we believe we can continue this momentum well into the future.

(*Id.* ¶ 108; Def. Ex. 10 at 5).

The complaint alleges that the italicized statements were false and misleading because "of the immediate and significant impact the PML death had on Tecfidera sales in late 2014 and into 2015." (Compl. ¶ 109).

3. January 29, 2015—Annual Earnings Call and Guidance

a. 2015 Revenue Guidance

On January 29, 2015, Biogen issued a Form 8-K containing a press release in which it announced 2014 earnings and released full-year 2015 financial guidance. The company projected annual revenue growth of 14 to 16 percent for 2015. (*Id.* ¶ 102).[12] The complaint alleges that defendants' failure to disclose (1) the steep decline in Tecfidera sales, including the impact of "slowing new starts and high discontinuation rates," and (2) the "true impact of the PML death on physician confidence in Tecfidera" rendered Biogen's guidance false and misleading. (*Id.*).

b. Earnings Call

Later that day, Scangos, Clancy, and Kingsley gave opening statements and responded to

[12] As with many of defendants' statements, the press release contained a caution concerning forward-looking statements. (Def. Ex. 11 at 10).

analysts' questions during Biogen's earnings call. The complaint alleges that defendants made the following false and misleading statements during their opening statements.

> Scangos: Tecfidera is in its second year on the market in the US in 2014. We successfully launched Tecfidera in the EU and are continuing to expand its presence across the globe. Tecfidera is now the most prescribed MS therapy in Germany and the most prescribed oral therapy in the US, with more than 135,000 people having been treated worldwide.
>
> As you all know from the IMS data, Tecfidera did experience moderating growth in Q4, which we believe is due to a variety of factors that Tony [Kingsley] will discuss in more detail. **However, we believe that *Tecfidera will continue to grow in [the] US* and will grow substantially in international markets, so that *we anticipate that 2015 will be another year of meaningful growth for Tecfidera* and for our portfolio of MS products, in general.**

(*Id.* ¶ 111; Def. Ex. 12 at 3). The complaint alleges that the italicized statements were false and misleading because "Tecfidera sales had declined in almost every region by the end of 2014 and into 2015, leading [Biogen] to lower Tecfidera sales goals by January 2015." (Compl. ¶ 112).

> Kingsley: Tecfidera continued to demonstrate its strong performance, which we believe is a testament to its attractive product profile, combining strong efficacy, favorable safety and tolerability, and the convenience of oral administration. We believe Tecfidera is on track to become the most prescribed therapy for MS worldwide.
>
> As you may have seen through IMS, we observed moderating new starts for Tecfidera in the fourth quarter. We believe several factors have impacted the recent performance of Tecfidera, including a decline in the overall market switch rate, the US label update in December, and the recent launch of [Biogen's new MS drug] Plegridy, which is capturing some interferon switches that otherwise may have gone to Tecfidera.
>
> ***Importantly, we have not noticed a meaningful change in Tecfidera discontinuation rates.*** **We are actively engaging physicians to ensure proper education on the label update.** ***And we believe in the continued growth potential of the product in the US.***

(*Id.* ¶ 113; Def. Ex. 12 at 5). The complaint alleges that the statements in italics were false and misleading because Kingsley "knew sales were down in almost every region in the United States" and because he "admitted after the class period that defendants knew that the PML death

had led to a significant change to the safety profile of physicians' confidence in Tecfidera."

(Compl. ¶ 114).

> Clancy: Let me turn to our full-year 2015 guidance. In 2015, we plan to provide annual guidance in one update per year during our second-quarter earnings. This modest change is intended to synchronize with our internal planning processes and ensure a continued focus on the long-term.
>
> Now, starting with revenues. ***We expect revenue growth between 14% and 16%.***
>
> Before I provide color on the products, I'd like to highlight three factors. First, our plan assumes exchange rates at the recent spot rate. Second, as a reminder, we expect a year-over-year decrease in royalty revenue of approximately $130 million as the royalties on Angiomax sales have expired. Third, our plan assumes our one year of free pricing in Germany for Tecfidera will end this March and move to a lower price.
>
> Now, let me characterize how we're thinking about each of our products. ***Our plan assumes Tecfidera will represent the largest contributor to our overall revenue growth.*** In Europe, our planned assumes Tecfidera will have full reimbursement in the majority of the EU market.

(*Id.* ¶ 115; Def. Ex. 12 at 7). The complaint alleges that the italicized statements were materially false and misleading because "by late 2014, Tecfidera sales had steeply declined in almost every region in the United States." (Compl. ¶ 116).

The complaint alleges that Clancy and Kingsley made the following statements as the call turned to questions from analysts.

> Question: I apologize up front. I'm really going to ask you to do our job at one level. On Tecfidera, looking at long-term consensus numbers—I know these numbers [are] noisy—it looks like average 2020 [analyst] estimates around $9 billion, implying a global market share of around 40%. Interested in your view and whether you think the Street may have got ahead of itself, here? Or if you think that Tecfidera is likely to get to those levels of market share?
>
> Clancy: Gosh, [analyst name], we don't give long-term guidance out there. And so I think we're going to stay at that as it is. And let people come to their same conclusions.
>
> ***We think this is still a very meaningful growth with Tecfidera that's embedded in the guidance for this year.*** But I wouldn't want to comment on a bunch of

models over a long period of time.

(*Id.* ¶ 117; Def. Ex. 12 at 10-11). The complaint alleges that the italicized statement was materially false and misleading because Clancy "failed to disclose that by late 2014 and into 2015 sales were down in almost every region in the United States." (Compl. ¶ 119).

> Question: And then secondly, you mentioned three different reasons Tecfidera was weaker—it was weaker or slowing down, in terms of new patient adds. And it was a decline in switching, [the] US label change, and the Plegridy launch? Of the three, which one was the most important?
>
> . . . .
>
> Kingsley: On Tecfidera—look. Actually hard to piece apart. Probably the—as Paul said, we expect the product to grow. But we would see some moderation in growth next year.
>
> I think we would have said that in any case for the first reason, which is the switch rate in the US has come down over the last three or four quarters. We've talked about that, I think, again, pretty consistently. When Tecfidera launched in the US—and we're seeing this repeat outside the US—it doubled or tripled the switch rate for a period of time. And that's been working its way down over time.
>
> . . . .
>
> Question: A question for Tony [Kingsley]. You mentioned one of the causes of Tecfidera slowdown recently has been label change. But **interestingly, you're not seeing any increase in discontinuations**, which, I guess, you'd presumably get with more aggressive lymphocyte monitoring. So I'm curious—**what are you seeing, in terms of physician reactions to the [PML] case that might be selling uptake, and what sorts of educational initiatives do you think will be needed to help physicians work around this?**
>
> Kingsley: Thanks good question. I think the educational initiatives are underway, which is, we have sales forces out, talking to a broad set of physicians. Our medical team is providing support where there are requests. So I think we are [executing on this]—educating people to the label and what the label says. And answering those questions.
>
> You know, part of the impact, when you have something like this, is the time it takes to get. You can get to a small set of physicians quickly, and you tend to get to the KOLs quickly [as the] time to get to broader community base.
>
> ***So we think we have the right education in place. We have to keep executing it***

> ***and making sure that things continue to happen.***
>
> Look—***the lack of any meaningful change that we see—or we believe we're seeing—in the discount[inuation] rate is encouraging because it doesn't suggest there's such a change in the profile that people are anxious to pull patients off, but on the contrary.*** Look—I think that, naturally, in a case like this, as people are processing the new label, you'll see softness in switch rate for a period of time. And that is, probably, what accounts for it.

(*Id.* ¶ 117; Def. Ex. 12 at 11-13). The complaint alleges that the italicized statements were materially false and misleading because "defendants knew sales were down in almost every region of the United States" and because Kingsley "admitted after the class period that defendants knew the PML death had led to a significant change to the safety profile and physicians' view of Tecfidera." (Compl. ¶ 118).

4. <u>February 25, 2015—Kingsley at Conference</u>

The complaint alleges that Kingsley made several false and misleading statements about Tecfidera's "safety profile and discontinuation rate" during a healthcare conference on February 25, 2015.

> <u>Question</u>: Why don't we just start high-level? Fourth quarter, there was some Wall Street nervousness a little bit about the fourth quarter. Analysts were all predicting a Tecfidera miss, but you guys came out and surprised. **So maybe talk a little bit about what you're seeing with Tecfidera since 2014 and how we should be thinking about Tecfidera for 2015.**
>
> <u>Kingsley</u>: Yes, good question. So look, ***we think Tecfidera is a terrific product that's continuing to perform very well in the market***. It's—from the time it launched, it has really driven a lot of conversion in the market—or acceleration in the conversion of the market to orals. **It's got a good profile. We position it as a great first-line therapy and a great switch-to therapy, and that's where the source of our business comes. *We've talked in the past, we're getting about 1/3 of new starts, which is a very good thing, and we're getting a nice portion of the switch pool as well.***
>
> If I look across 2014, we expected—have expected to see the Tecfidera trend rate come down from a pace of growth over time. When Tecfidera launched, it accelerated the market growth significantly. It brought probably positive balance in the returning quitters versus quitters pool, but it also stimulated a switch market

that was multiples of what it had historically been.

Question: So switch, so people were quick to switch off onto Tecfidera, so you got that big bump, and quitters and those outside the market also came back in, in the therapy [ph] that caused some exceedingly . . .

Kingsley: Yes, it was—right. It was probably positive. So just this—even the switch pool itself was probably running at, at 1.3x and then 2x what you would see as a normal historical average.

Question: Twice the speed [ph], okay.

Kinsley: So there's a piece of Tecfidera performance in '14 which in the U.S. is a slowing of the growth rate, which we had predicted and talked about and it made total sense. We—what we look at with Tecfidera and across the portfolio is what's the capture rate? What's the capture rate at naives, which is a relatively smaller portion but important to get it, and what's the capture rate of the switch pool? And as we went through the year, we still feel very comfortable with where Tecfidera is in terms of patient capture. **Fourth quarter, we had the report of 1 PML incident and I think we talked about this in earnings call and toward the end of the year which is that's a meaningful event that you have to manage through, right? There's a lot of communication that has to happen to physicians.** ***You would expect to see some hesitancy among some set of physicians before you get to them to have a conversation. But that would—the product's been quite resilient, I think, is our view in light of that. 2015, we think it's still a meaningful growth driver.*** U.S. will still see growth and we have geographic expansion as we're rolling out to more markets outside the U.S.

Question: **So in the fourth quarter, and that's important because we're thinking about Q1, do you think a lot of the sort of PML noise or news has gotten out there? And have you started to see a reacceleration of things when you go out into the—I think, what's the feedback from the sales force?**

Kingsley: Yes, so the information certainly got out in the fourth quarter. Looking at analogous situations with other products, we typically think you might have a 2, 3 month time frame where this presses, but that's looking at analogies. So impossible to predict with great accuracy. But look, ***I think the most positive message, I would say, on Tecfidera is if you're still capturing 1/3 of new starts, that makes a pretty strong statement about what the market's perception of the product is including safety. We have not seen any change in the discontinuation rate.*** There is a natural discontinuation rate for a product like Tecfidera in terms of [ph] tolerability and other things. ***You'd obviously get very concerned if you saw a spike in the discontinuation rate. No evidence of that.***

Question: **Do you think it's stable? Do you think discontinuation has been very stable?**

> Kingsley: ***It's been consistent with—I mean, we look at it relative to the growth of the product. There's nothing that's a signal that says it's not consistent with the historical averages.*** There's probably, and we talked about this, a little confounder in the fourth quarter and the first part of this year which is we launched Plegridy, which is our new interferon. Mathematically, a big piece of the source of Tecfidera's business, because it comes from injectables, is Avonex, right? So that has historically been a source of where Tecfidera switches have come from. Because we put some promotion around Plegridy and because it's a good alternative, a meaningful portion of Avonex patients have actually switched to Plegridy rather than some of those might have gone on to Tecfidera. That's why it's great to have a franchise. From a franchise standpoint, we're able collectively to capture a portion of that pool. So there's probably some perturbation in the number based on that, but we feel good about where the product is.
>
> Question: Okay. Now in the—you mentioned the PML, seeing [ph] that in the fourth quarter, that should start to get normalized if it takes a couple of months based on past examples. Plegridy, that hit in the fourth quarter. So that was a change, although from a franchise basis, that is net neutral. Now the margins on Plegridy is actually higher than Tecfidera? Similar? Higher?
>
> Kingsley: Pretty similar, pretty similar, I think. Pretty similar.

(*Id.* ¶ 128; Def. Ex. 10 at 4-5).

The complaint alleges that the italicized statements were false and misleading because "by late 2014 and into 2015, sales had declined in most regions" and because Kingsley "admitted after the class period that defendants knew the PML death had led to a significant change to the safety profile and physicians' views of Tecfidera." (Compl. ¶ 129).

5. March 2, 2015—Scangos at Conference

The complaint alleges that Scangos made the following false and misleading statement about Tecfidera during a healthcare conference on March 2, 2015.

> Scangos: We are a leader in the treatment of MS, as you all know there are worldwide about 800,000 patients being treated for MS that is a market of about $17 billion this year. That market is growing every year single digits, low single-digit growth every year and we expect that to continue over the coming years.
>
> Of those 800,000, we treat about 300,000. And so we treat more patients with

> more drugs than any other company. That's, you can do the math that's about a 37.5% market share, someone rounded up here. And **we believe it is growing and we'll continue to gain market share and that's a result of the four drugs you see here[.]** ***Tecfidera [is] certainly our main driver here continuing to grow, continuing to do well.*** Plegridy recently introduced for the treatment of MS, pegylated interferon dosed subcu once every two weeks, and Avonex and Tysabri are stand-by that we have for quite a while and those both continue to do well.

(*Id.* ¶ 131; Def. Ex. 15 at 3-4).

The complaint alleges that the italicized statement was false and misleading because Scangos "failed to disclose that sales had declined across the United States since late 2014 and into 2015, and that the Company had been forced to lower sales thresholds for sales teams." (Compl. ¶ 132).

6. April 24, 2015—First-Quarter-Earnings Call

On April 24, 2015, Biogen held its first-quarter-earnings call. It announced that Tecfidera and Biogen revenues that had declined 9.9 percent and 3.2 percent, respectively, from the previous quarter. According to the complaint, defendants, for the first time, "partial[ly] disclose[d] . . . the truth regarding patient and physician reaction following the PML death." (*Id.* ¶ 134). However, it alleges that "defendants continued to mislead the market regarding the true extent of the PML death's impact on Tecfidera sales" and that they made false and misleading statements "regarding Tecfidera performance while failing to update or correct earlier-issued FY 2015 guidance (and thus confirming it)." (*Id.* ¶ 135).

CEO Scangos led off the April 24 call:

> Scangos: Biogen had a mixed start to 2015. We made good progress on our pipeline, but our commercial results were not as strong as we had hoped. Although we achieved 20% revenue growth and 55% non-GAAP EPS growth, compared to the same quarter last year, we had expected to do even better.
>
> We saw moderating patient uptake of our oral Tecfidera in the US and Germany. And like other companies, we had foreign exchange headwinds.

> Our MS franchise continued to gain overall share this quarter, but at a moderating pace. Our interferon business continued to perform well driven by the recent introduction to Plegridy. Tysabri remained the therapy of choice for patients needing high efficacy.
>
> Tecfidera had a more challenging quarter, due to a number of issues, including an overall slowing of the MS market, the recent launch of Plegridy, the single PML case reported last year, and some first-quarter financial dynamics that Paul [Clancy] will discuss.

(Def. Ex. 17 at 3). Williams followed Scangos, and then Kingsley addressed the subject of Tecfidera:

> Kingsley: Let me start with the MS franchise. We continue to believe that our portfolio of products is a source of strength in the marketplace, with the leading oral agent, the leading high efficacy agent, and two well positioned interferon options. In the US, we believe we continue to capture roughly half of all newly diagnosed and switch patients within our franchise in Q1.
>
> As we've said in prior calls, with the launch of Tecfidera in 2013 in the US and 2014 in Europe, we saw a period where both market growth and switching dynamics were well above historical averages, and Tecfidera really drove this. And we expected a natural moderation in these rates through 2014 and into 2015. We believe this is occurring as expected, but also believe that the [Tecfidera] safety event in October further dampened market growth and switch rates in Q1.
>
> So in this broader market context, **Tecfidera continued to add patients this quarter, but at an overall slower rate.** ***In the US, our internal market research suggests that physician intent to prescribe may be improving. We believe these data indicate that we are assisting physicians in putting the updated label into context.***
>
> . . . .
>
> ***We continue to believe that Tecfidera remains the preferred oral option in the market, given its strong efficacy, convenience and safety profile.*** We are leveraging the full capabilities of our commercial organization to communicate these benefits. Maintaining significant sales force focus, executing both physician and patient programming with updated messaging, and increasing our share of voice across both print and digital media.

(Compl. ¶ 135; Def. Ex. 17 at 4-5). The complaint alleges that the italicized statements were false and misleading because "Tecfidera sales continued to be significantly lower following the

PML death" and because "defendants admitted after the class period that to the contrary [of Kingsley's assertion], Biogen's market research indicated a moderation in physician intent to prescribe." (Compl. ¶ 136).

Clancy continued the April 24 call as follows:

> Clancy: This quarter's Tecfidera revenues consist of $648 million in the US and $177 million outside the US. There are few items that impacted Tecfidera revenue in Q1. Let me provide the details.
>
> . . . .
>
> So [the lower number of] shipping weeks, [higher] gross to net [adjustments], foreign exchange [impact,] and German pricing negatively impacted Tecfidera this quarter. Nevertheless, as we have noted, we saw moderating patient growth, especially in the US and Germany, and we are working diligently to improve Tecfidera's trajectory.
>
> . . . .
>
> This brings us to our non-GAAP diluted earnings per share, which were $3.82 for the first quarter. As a reminder, last quarter, we announced our plan to provide annual guidance in one update per year during our second-quarter earnings. This change intended to synchronize with our internal planning processes and ensure a continued focus on the long term.
>
> As a result, ***we won't be updating our formal guidance this quarter***, though I would like to briefly characterize our thinking about the remainder of the year. There are two key items we are keeping a watchful eye on for the rest of the year.
>
> First, while foreign exchange has been a headwind, any additional strengthening of the dollar could exacerbate this impact on revenue. And second, ***we continue to expect Tecfidera will represent the largest contributor to our overall revenue growth.*** **If the US trajectory does not improve, we may come in at the lower end of our previously provided revenue growth.**

(*Id.* ¶ 135; Def. Ex. 17 at 5-6). The complaint alleges that the italicized statements were materially false and misleading "because the 14 [to] 16 [percent revenue growth] metric was no longer achievable based on Tecfidera sales trends as of March 2015." (Compl. ¶ 137).

Scangos closed the April 24 call as follows:

> Scangos: In closing, the year is shaping up to be an eventful one for us. **Obviously, a top priority for us is the growth of our entire MS portfolio, including Tecfidera. We believe that Tecfidera is a compelling treatment option for MS patients, and *our long-term outlook for Tecfidera, and for our entire MS portfolio, remains strong.***
>
> We believe that our portfolio provides leading choices for patients among interferon, oral, and high efficacy therapies, and we are working hard to overcome the headwinds that we saw last quarter.

(*Id.* ¶ 135; Def. Ex. 17 at 6). The complaint alleges that the statement was materially false and misleading because "Tecfidera's trajectory had changed immediately following the announcement of the PML death, and sales continued to be down across the United States, forcing [Biogen] to lower compensation thresholds [for sales employees]." (Compl. ¶ 138).

7. May 6, 2015—Clancy at Conference

The complaint alleges that Clancy made the following false and misleading statement about Tecfidera during a healthcare conference on May 6, 2015.

> Question: So let's talk, I mean, start first, I thought we'll talk about Tecfidera, so it's really coming out of JPMorgan, you know I think that you guys did a good job of sort of reminding us that maybe the PML case might have an impact on Tecfidera. And then, [fourth] quarter was amazing. And so we kind of forgot about it. Then first quarter sort of surprised us again, maybe could you just give us your thought process about the last few months, and when you really started thinking that this might have a little bit of an impact or more of an impact than we thought?
>
> Clancy: Yes, so I mean, I'll tie back most of my comments to kind of our comments in first-quarter-earnings call. . . . The company overall drove in aggregate 20% top line growth [1Q15 over 1Q14] and in well north of that in the bottom line, but it was short of our expectations and I think, short of the street expectations as well. So we weren't pleased with the Tecfidera performance, as we came through the first quarter of 2015 particularly in the United States.
>
> And I think we got a bunch of work to do as we move forward. It appears to be a number of factors that have kind of happened and that you know—it is a little bit hard to discern and [at]tribute how much is to one thing versus the other. I mean, certainly as you noted that there was a safety event that we talked about in October on Tecfidera that seems to have had a little unfavorable impact on the safety perceptions that we saw register in a number of our—kind of the way we

> kind of do attitudinal surveys with physicians, that has stabilized. . . . But I think it was—it didn't turn around or it hasn't turned around as quick as we had wanted it to turn around.
>
> . . . .
>
> Question: The people ask me all the time, do I think that Biogen can reaccelerate share, the status quo, and I remember with Avonex and Tysabri, both times you've reaccelerated market share. So help me understand how long does it take– – what's the worst case here to turn this around? See you're putting from number three to number one or you're switching it around, what kind of effect could that have on Plegridy? What does that mean for a sales person to re-put Tecfidera in the first place, and when are they motivated to see a change in market share?
>
> Clancy: Yes, we were all motivated. We are all motivated to get it done, you know, the priority number one, no doubt about it across the company. Just literally hard to kind of forecast when it's actually going to happen. ***But we fundamentally believe that we got, we still have upward trajectory on Tecfidera from a share perspective, from a patient perspective,*** **no doubt about it.**

(*Id.* ¶ 139; Def. Ex. 18 at 2-3).

The complaint alleges that the italicized statement was false and misleading because "he knew that the current trajectory of Tecfidera in the United States had changed immediately after the PML death, and that it still had not recovered at the time of the misleading statement." (Compl. ¶ 140).

8. May 13, 2015—Williams at Conference

The complaint alleges that Williams (who is not a named defendant in this case) made the following false and misleading statement about Tecfidera in response to a question during a healthcare conference on May 13, 2015.

> Question: I have a question on PML. So we are seeing the growth of—considering the US market is slowing down a little bit because of (inaudible) PML report, what are you communicating to the physicians with regard to risk mitigation of PML? And do you think we might see more cases of PML associated with Tecfidera with patients taking Tecfidera for longer time?
>
> Williams: Yes, I think—we talked about this in the earnings call, I think quite clearly there was an impact of the single PML case with Tecfidera in the market,

did slow down I think the rate at which new patients were started on the drug.

We've done some survey work recently that would suggest that physicians have kind of digested the information, taken it on board and their perspective about the safety profile of the drug has kind of gotten back to where it was before the PML event. **That's sort of the first step in being able to get back on that trajectory of putting new patients on the drug.**

I think that what we've being saying to physicians is really just citing the facts and staying with the label which has evolved a little bit as a result of this. This is basically no change in the risk benefit profile for the drug. We've got I think 70,000-plus patients, 80,000-plus patient years on the drug. So we've got quite a bit of experience now and this single case is sort of not outside the background rate.

I think the other thing to point out is that for orals, for other drugs in the space, I mean we've just recently seen a non-confounded case with Gilenya as well. So I think there is some background incidents in MS patients treated for the long term that will be kind of part and parcel of the treatment landscape. But I think same is true for Gilenya, the same is true for Tecfidera.

I don't think that those singular cases change the benefit risk profile for the drug in any way. That's really what we have been communicating to physicians. I think over time, they have taken that on board and we started to see that in their perception of the drug.

(*Id.* ¶ 141; Def. Ex. 19 at 6-7).

The complaint alleges that the italicized statements were false and misleading because "defendants failed to disclose that sales of Tecfidera across the United States had not recovered to the level prior to the PML death" and because "Kingsley also admitted after the class period that defendants knew the PML death had led to a significant change to the safety profile and physicians' view of Tecfidera." (Compl. ¶ 142).

9. <u>May 19, 2015—Kingsley at Conference</u>

The complaint alleges that Kingsley made the following false and misleading statements about Tecfidera during a healthcare conference on May 19, 2015.

<u>Question</u>: And so when you think about—just staying on Tecfidera for a minute as it relates to the demand trends, right, so you said on the last quarter call that

> you're working to basically continue to stimulate the demand. You're seeing that there's a lot of organic demand in the product, but we've seen in the last couple quarters that maybe the trend just flattened out a little bit. So, but it sounds like you have some confidence that there are things that can be done to increase the trend line there. So what is that we should be thinking about and what is it can be done from an operational perspective?
>
> Kingsley: Look, ***we still think Tecfidera has the best profile in the market*.** **It is the best profile, the oral in a market that is moving toward orals.** We did talk about the safety event at the end of last year having an impact on Tecfidera, but frankly on the market as a whole, right the whole market, patient switching has slowed down substantially.
>
> So we've got the profile. We have the new label with the updated safety data that we've been able to communicate to physicians and promote to. Look, a lot of what we're focused on with Tecfidera because we think they have the great profile is reach and frequency, messaging and emphasizing the efficacy, which is the big differentiation and the great safety profile of Tecfidera.
>
> We have patient directed marketing, direct-to-patient marketing through various channels, digital channel. We're also emphasizing that because that's important in a time where there's been probably some patient hesitance in the market and a significant amount of educational programming. So a lot of basics actually that you need to dig it on and keep focusing again. **We like the profile and *we think we can execute to continue growth*.**

(*Id.* ¶ 143; Def. Ex. 20 at 3).

The complaint alleges that the statements in italics were false and misleading because "Tecfidera sales ha[d] declined since late 2014" and because "Kingsley also admitted after the class period that physicians views of Tecfidera's safety profile had not yet recovered." (Compl. ¶ 144).

10. May 27, 2015—Clancy at Conference

Finally, the complaint alleges that Clancy made the following false and misleading statements about Tecfidera during a strategic decisions conference on May 27, 2015.

> Question: Most of your revenue today comes from your MS portfolio broadly and you had a spectacular success last year with Tecfidera launch. The script trend looks as though it's pretty flat for [Tecfidera] now and maybe you could talk us through your thinking about the outlook for [Tecfidera]. Is this flat

trend going to be long term or do you think there's just . . . patients that you have to work your way through and then you get back to a sort of underlying growth trend? If you were sort of thinking about what the growth potential of the MS franchise is, how should we think about it?

Clancy: It's a great question. It's a little bit like it's ahead of us, it's a very important question for us, we're studying it hard. Let me kind of try to put it little bit in context. We were disappointed with the first-quarter results on Tecfidera, I think we kind of used those words on the call. I think it was a confluence of factors that all kind of came together. Certainly **there was a safety event late last year *where physician perceptions on the safety profile declined a little bit,* still in a very good competitive profile vis-a-vis other therapies in the marketplace. *Those have stabilized, right.*** First order of business of turning it around hasn't [inaudible] those perceptions yet, but they've actually stabilized. The second thing about the same time late last year we launched Plegridy and we took a little bit of allocation of our sales force's time and focus and incentive comp and moved it towards that launch.

In hindsight maybe we would have done things differently. The third point is that we actually had seen some of this slowing going on dating actually back to the summer of last year in the US marketplace. And I think probably the better way to put that in perspective is people saw that and really kind of measured it up to such an incredibly strong launch. So as we marched through the three quarters of the US launch in the United States in 2013, it was remarkable, it far exceeded our expectations. And essentially we brought back into disease modifying therapies a number of patients that were quote-unquote on the sidelines or quitters and remember, this was a market that had been served for a decade-and-a-half with injectable therapies. So, a lot of people had kind of moved to the sidelines and Tecfidera brought a lot of those patients back we believe and it really accelerated the amount of switch rates in the marketplace.

We always knew that that would begin to moderate. I think all of these factors kind of happened roughly at the same period of time. I don't know where kind of the next number of quarters go. I think we're into really addressing this. We've reallocated resources back to Tecfidera and it's the primary focus, which is absolutely the right thing to do. We're educating physicians around and putting in context the safety profile, the risk benefit profile, and the strong efficacy that Tecfidera fundamentally has, and we're opening up a bit on direct to consumer like prints, like digital. So, I think we're into a very much a blocking and tackling. **We continue to see our share of capturing of new scripts and switched scripts higher than our share. *That's usually an indication that we'll get upward momentum in the business.***

This business is characterized simultaneously that you got to get that upward momentum because sometimes patients switch off of your therapy so that's going

> to be attention in the business. But I think it comes down to good blocking and tackling, ***we'd be surprised if we don't see forward momentum from here.***

(*Id.* ¶ 145; Def. Ex. 21 at 3-4).

The complaint alleges that the statements in italics were false and misleading because "he failed to disclose that Tecfidera sales had significantly declined since late 2014" and because "defendants also admitted after the class period that views of Tecfidera had not yet recovered." (Compl. ¶ 146).

E. Additional Scienter Allegations

In addition to the statements from the confidential witnesses, the complaint includes other allegations that plaintiffs contend bolster the inference that defendants had the requisite scienter (that is, that they had the conscious intent to defraud investors or acted with a high degree of recklessness).

First, the complaint alleges that Tecfidera was Biogen's core product and that the individual defendants had immediate access to sales numbers and feedback from physicians after the PML death. (*See id.* ¶¶ 159-67, 173-75). It alleges that Tecfidera was Biogen's main revenue source throughout the class period, accounting for more than one-third of the company's total revenue. (*Id.* ¶ 159). In the company's SEC filings and public statements, defendants repeatedly stated that Tecfidera was the company's "principal product," "major business driver" and "largest contributor to overall revenue growth." (*Id.* ¶¶ 160-65). It also alleges that defendants had insider access to—and therefore awareness of—Tecfidera's "daily" sales and market research of physicians' safety perceptions. (*See id.* ¶¶ 166-67). According to the complaint, Kingsley, as a result of his close proximity to Biogen's sales force, "was aware of, or was reckless in not being aware of, the immediate and significant impact the PML death had on sales of Tecfidera and physician-prescribing patterns." (*Id.* ¶ 175).

Second, the complaint alleges that Scangos and Clancy had both the motive and opportunity to misrepresent Tecfidera sales, because they "profited from meeting bonus targets based on revenue growth, which in turn depended mainly on Tecfidera growth." (*Id.* ¶ 168). According to publicly filed SEC Forms 4 submitted by defendants, Scangos, Clancy and Kingsley were all net-acquirers of Biogen shares during the class period. (*See* Def. Ex. 26-28). According to those forms, Scangos acquired 29,915 Biogen shares through vesting of restricted stock and sold 6,810 shares, although neither Clancy nor Kingsley sold any shares during the class period. (*Id.*). The complaint also alleges that Biogen authorized a $5 billion share repurchase program in May 2015, "two months before the full disclosure of the truth regarding Tecfidera's performance following the PML incident." (Compl. ¶¶ 171-72).

II. Procedural Background

The original complaint in this case was filed on August 18, 2015. On November 18, 2015, the Court appointed GBR Group, Ltd. as lead plaintiff and granted plaintiffs' request for an additional sixty days to file an amended complaint. On January 19, 2016, GBR filed a complaint on behalf of all purchasers of Biogen's publicly traded securities, including common stock and exchange-traded options on Biogen common stock, during the period from December 2, 2014, through July 23, 2015. The complaint alleges that Biogen and the individual defendants violated Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 (Count One); that Biogen and the individual defendants violated Rules 10b-5(a) and 10b-5(c) under a theory of "scheme liability" (Count Two); and that the individual defendants violated Section 20(a) of the 1934 Exchange Act (Count Three).

Defendants have moved to dismiss the complaint with prejudice. Defendants contend that Count One should be dismissed under Fed. R. Civ. P. 9(b) and 12(b)(6), and the PSLRA, 15

U.S.C. §§ 78u-4, 78u-5 for two reasons: (1) failure to allege an actionable misstatement or omission; and (2) failure to satisfy the PSLRA's requirement of pleading specific facts giving rise to a strong inference of scienter. Defendants have moved to dismiss Counts Two and Three for failure to plead a "scheme" to defraud, and failure to adequately plead an underlying Exchange Act violation. In their opposition to defendants' motion to dismiss, plaintiffs concede that Count Two should be dismissed.

III. Legal Standard

On a Rule 12(b)(6) motion to dismiss a claim brought under Section 10(b) and Rule 10b-5, courts must, as with any such motion, accept plaintiffs' allegations as true. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). However, Congress has raised the standard of pleading for Section 10(b) and Rule 10b-5 securities fraud claims.[13]

When a plaintiff alleges misrepresentation or omission of a material fact, the PSLRA requires that the complaint "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1); *accord Fire and Police Pension Ass'n of Colo. v. Abiomed, Inc.*, 778 F.3d 228, 240 (1st Cir. 2015). "A fact is material when there is 'a substantial likelihood' that a reasonable investor would have viewed it as 'significantly alter[ing] the total mix of information made available.'" *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp.*, 632 F.3d 751, 756 (1st Cir. 2011) (alteration in original) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988)). "A statement can be 'false or incomplete' but not actionable 'if the misrepresented fact is otherwise

[13] "In 1995, Congress enacted legislation attempting to wrest control over securities fraud class action lawsuits from the plaintiffs' bar devoted to such litigation and confer it upon counsel for larger institutional investors. Such a measure, it was believed, would cut down on frivolous litigation as counsel for institutional investors were thought to take a more balanced cost-benefit view of such litigation. While at it, Congress raised the hurdle a plaintiff would have to jump before being permitted to present her case to a jury." *Lirette v. Shiva Corp.*, 27 F. Supp. 2d 268, 271 (D. Mass. 1998) (internal citations omitted).

insignificant.'" *Id.* at 756-57 (quoting *Basic*, 485 U.S. at 238). However, "while a company need not reveal every piece of information that affects anything said before, it must disclose facts, 'if any, that are needed so that what was revealed [before] would not be so incomplete as to mislead.'" *In re Cabletron Sys., Inc.*, 311 F.3d 11, 36 (1st Cir. 2002) (quoting *Backman v. Polaroid Corp.*, 910 F.2d 10, 16 (1st Cir. 1990) (en banc)).

"'The PSLRA also separately imposes a rigorous pleading standard on allegations of scienter.'" *Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 240 (quoting *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 58 (1st Cir. 2008)). To plead scienter, the complaint must "with respect to each act or omission . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). A strong inference is "more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of non-fraudulent intent." *Tellabs*, 551 U.S. at 314. "A complaint will survive a motion to dismiss only if it states with particularity facts giving rise to a 'strong inference' that defendants acted with a conscious intent 'to deceive or defraud investors by controlling or artificially affecting the price of securities' or 'acted with a high degree of recklessness.'" *Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 240 (quoting *Waters Corp.*, 632 F.3d at 757). "Recklessness, as used in this context, 'does not include ordinary negligence, but is closer to being a lesser form of intent.'" *Id.* (quoting *Greebel*, 194 F.3d at 188).

In evaluating the adequacy of a complaint, a court "cannot hold plaintiff to a standard that would effectively require them, pre-discovery, to plead evidence." *Mississippi Pub. Emps. Ret. Sys. v. Boston Sci. Corp.*, 523 F.3d 75, 90 (1st Cir. 2008) (quoting *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1225 (1st Cir. 1996)). However, a plaintiff may not simply rely on a "fraud by hindsight" theory of scienter—that is, "a plaintiff may not simply contrast a defendant's past

optimism with less favorable actual results, and then contend that the difference must be attributable to fraud." *Shaw*, 82 F.3d at 1223 (internal quotation marks and alteration omitted), *abrogated on other grounds by* 15 U.S.C. § 78u-4(b)(2). Courts should look at the complaint "as a whole" and weigh "competing inferences" in a "comparative evaluation" of plaintiffs' allegations and alternative inferences from those allegations. *ACA Fin.*, 512 F.3d at 59; *see also Tellabs*, 551 U.S. at 314. If "there are equally strong inferences for and against scienter," then the tie goes to the plaintiff. *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 45 (1st Cir. 2008) (quoting *ACA Fin.*, 512 F.3d at 59).

IV. Analysis

Distilled to its essence, the complaint alleges that immediately after Biogen announced the PML death in October 2014, Tecfidera sales did not just slow, but instead dropped "steeply" because physicians became reluctant to prescribe the drug. (Compl. ¶ 18). Based on statements from confidential sources, among other things, the complaint alleges that defendants must have known—and, indeed, did know—that the PML death was having a meaningful effect on Tecfidera sales as early as November 2014, before the class period started. The complaint alleges that "at no time during the class period [from December 2, 2014 through July 23, 2015] did defendants provide any indication that the PML death had materially impacted Tecfidera sales, or caused physicians to stop prescribing Tecfidera or switch patients onto other therapies out of safety concerns." (*Id.* ¶ 17).

Accordingly, the complaint alleges that defendants' statements during the class period were materially false by misrepresentation and omission, and that defendants knew or recklessly disregarded that their statements were materially false and misleading. In addition to the Rule 10b-5 claim (Count One), the complaint also asserts a claim for "scheme" liability under Rule

10b-5(a) and (c) (Count Two), and a claim against the individual defendants as control persons under Section 20(a) of the Exchange Act (Count Three).

Defendants contend that Count One should be dismissed for two principal reasons. First, they contend that the Rule 10b-5 claim should be dismissed because the complaint fails to adequately plead an actionable misstatement or omission. Specifically, defendants contend that the alleged actionable statements are either (1) forward-looking statements protected by the PSLRA's safe harbor provisions, (2) non-actionable statements of corporate optimism or puffery, or (3) not adequately alleged to be false or misleading. Second, they contend that Count One, as well as Count Two, should be dismissed because the complaint fails to allege specific facts giving rise to a strong inference of scienter. Defendants also contend that Count Three should be dismissed for failure plead a predicate Exchange Act violation.

A. Count One: Rule 10b-5 Generally

Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful "[t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe." 15 U.S.C. § 78j(b). Pursuant to that section, the SEC promulgated Rule 10b-5, which makes it unlawful:

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,
>
> in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5. "To state a claim for securities fraud under Section 10(b), a plaintiff

must allege: "(1) a material misrepresentation or omission; (2) scienter, or a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." *In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 40 (1st Cir. 2014); *accord Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 240.

Only the first two elements are at issue here. The Court will address the complaint's allegations of material misrepresentations and omissions before turning to the issue of scienter.

B. Allegations of Material Misrepresentations and Omissions

The complaint alleges that defendants made more than twenty misrepresentations and omissions that materially understated the actual effect that the PML death was having on Tecfidera sales. Defendants contend that none of the defendants' statements are actionable under Rule 10b-5 for three reasons.[14]

1. Forward-Looking Statements

First, defendants contend that many of the statements are protected by the PSLRA safe harbor provisions for "forward-looking" statements. (*See* Compl. ¶¶ 102, 108, 111, 113, 115, 117, 131, 135). Specifically, they contend that defendants' formal revenue projections as well as any statement prefaced by "we believe" are protected forward-looking statements. Plaintiffs counter by contending that (1) the safe harbor provisions do not apply to material omissions, (2) defendants' statements about the future of Tecfidera were based on then-current facts, and

[14] Defendants provide a fourth reason why the complaint fails to plead an actionable misrepresentation or omission: both before and throughout the class period, Biogen informed investors that Tecfidera growth was slowing due to a number of factors, including the PML death. (Def. Mem. 21). Defendants' argument is not entirely without merit. *See In re The First Marblehead Corp. Sec. Litig.*, 639 F. Supp. 2d 145, 155 (D. Mass. 2009) ("A plaintiff fails to plead an actionable [Section] 10(b) claim predicated on the concealment of information if that information was, in fact, disclosed."). However, defendants' argument misinterprets the complaint's allegations. The complaint does not allege that defendants concealed the PML death itself, or even that they represented that it would not have *any* effect on Tecfidera sales. Rather, it alleges that defendants misrepresented and omitted the alleged *substantial* effect that the PML death was having on Tecfidera sales. The dispute is essentially one of degree, and the Court will not dismiss the claim on those grounds.

therefore are not forward-looking, and (3) defendants' cautionary language was not sufficiently meaningful and tailored to the October 2014 PML death.

The PSLRA provides, with certain limitations, that issuers of securities shall not be liable in any private action based on an untrue or misleading statement of a material fact "with respect to any forward-looking" statement if the statement is

> identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement, . . . or . . . the plaintiff fails to prove that the forward-looking statement . . . [if made on behalf of a business entity by or with the approval of an executive officer was] made . . . with actual knowledge by that officer that the statement was false or misleading.

See 15 U.S.C. § 78u-5(c)(1); *In re Stone & Webster, Inc. Sec. Litig.*, 414 F.3d 187, 211-12 (1st Cir. 2005). The statute defines "forward-looking" statements to include

> (A) a statement containing a projection of revenues, income . . . earnings (including earnings loss) per share, . . . capital expenditures, dividends, . . . or other financial items; (B) a statement of the plans and objectives of management for future operations . . . ; (C) a statement of future economic performance . . . ; (D) any statement of the assumptions underlying or relating to [any of the above].

15 U.S.C. § 78u-5(i)(1); *accord In re Stone & Webster*, 414 F.3d at 212.

"Forward-looking statements are often contained in financial filings. Congress, in providing the limited safe harbor protection, sought to encourage market efficiency by encouraging companies to disclose future projections without fear that those projections, if they did not materialize, would result in an action for fraud." *In re Biogen IDEC, Inc. Sec. Litig.*, 2007 WL 9602250, at *10 (D. Mass. Oct. 25, 2007) (citations omitted), *aff'd sub nom. New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35 (1st Cir. 2008). "When faced with an arguably forward-looking statement, the future projections must be identified and separated from the present facts upon which those projections are based." *Id.*

(citing *In re Stone & Webster*, 414 F.3d at 212-13). "The statutory protection will . . . apply [only] where the claim of fraud is based upon the future projection." *Id.*

The following alleged misrepresentations in Biogen's financial projections squarely fall within the statutory safe harbor for "forward-looking" statements concerning projected earnings and "future economic performance." *See* 15 U.S.C. § 78u-5(i)(1)(A), (C); *In re Biogen*, 2007 WL 9602250, at *10.

- Biogen's January 29, 2015 fourth-quarter-earnings press release: "Revenue growth is expected to be approximately 14% to 16% compared to 2014." (Compl. ¶ 102).
- Clancy during January 29, 2015 earnings call: "We expect revenue growth between 14% and 16% . . . . Our plan assumes [Tecfidera] will represent the largest contributor to our overall revenue growth." (*Id.* ¶ 115).
- Scangos during the same call: "We anticipate that 2015 will be another year of meaningful growth for Tecfidera." (*Id.* ¶ 111).
- Clancy during April 24, 2015 earnings call: "[W]e won't be updating our formal guidance this quarter . . . . [W]e continue to expect [Tecfidera] will represent the largest contributor to our overall market growth. If the US trajectory does not improve, we may come in at the lower end of our previously provided revenue growth." (*Id.* ¶ 135).[15]

Moreover, those forward-looking statements were accompanied by adequate cautionary language. *See* 15 U.S.C. § 78u-5(c)(1) (providing safe harbor to forward-looking statements "accompanied by meaningful cautionary statements identifying factors that could cause actual

[15] The alleged misrepresentations in paragraphs 108, 113, and 131 of the complaint will be discussed in the section below concerning puffery.

results to differ materially from those in the forward-looking statement"). The fourth-quarter press release contained an explicit safe harbor statement (Def. Ex. 11), and it also referred investors to the risk factors listed in Biogen's SEC filings, which stated as follows:

> If we fail to successfully execute on our commercialization efforts for Tecfidera, our future revenue growth . . . may be adversely affected, and our stock price may decline. . . . Factors that may prevent us from successfully commercializing Tecfidera include: . . . damage to our sales and reputation, and physician and patient confidence in Tecfidera relating to any adverse experiences or events that may occur with patients treated with Tecfidera, *including any PML cases* . . . .

(Def. Ex. 2, 3, 5) (emphasis added); (*see also* Def. Ex. 13 at 25, 2014 Form 10-K) (noting that "safety warnings that may be required to be included in the label of our products, such as the risk of developing [PML] . . . in the U.S. label for Tecfidera, may significantly reduce expected revenues"). During the earnings calls, the company provided adequate forward-looking statements cautions and referred investors to its SEC filings for a full statement of risk factors. (Def. Ex. 12 at 3; Def. Ex. 17 at 3).

In summary, some of the alleged misrepresentations are protected by the PSLRA safe harbor provisions for "forward-looking" statements, and are therefore not actionable.

2. Statements of Optimism or Puffery

Defendants next contend that most of the alleged fraudulent statements are generic expressions of corporate optimism, or "puffery," that are immaterial as a matter of law. (*See* Compl. ¶¶ 106, 108, 111, 113, 117, 128, 131, 135, 139, 141, 143, 145). Plaintiffs counter by contending that the statements in question are "concrete, verifiable, and demonstrably false." (Pl. Mem. 26).

"In general, the materiality of a statement or omission is a question of fact that should normally be left to a jury rather than resolved by the court on a motion to dismiss." *In re Cabletron Sys.*, 311 F.3d at 34. Nonetheless, "not every unfulfilled expression of corporate

optimism, even if characterized as misstatement, can give rise to a genuine issue of materiality under the securities laws." *Shaw*, 82 F.3d at 1217.

> In particular, courts have demonstrated a willingness to find immaterial as a matter of law a certain kind of rosy affirmation commonly heard from corporate managers and numbingly familiar to the marketplace—loosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker, that no reasonable investor could find them important to the total mix of information available.

Id. "The corporate puffery rule applies to loose optimism about both a company's current state of affairs and its future prospects." *In re Boston Sci. Sec. Litig.*, 2011 WL 4381889, at *11 (D. Mass. Sept. 19, 2011), *aff'd*, 686 F.3d 21 (1st Cir. 2012) (citation omitted). However, "[b]ecause 'the recent trend is to consider expressions of corporate optimism carefully' . . . claims of puffery now require a court to consider (1) 'whether the statement is so vague, so general, or so loosely optimistic that a reasonable investor would find it unimportant to the total mix of information' and (2) 'whether the statement was also considered unimportant to the total mix of information by the market as a whole.'" *Id.* (quoting *Brumbaugh v. Wave Sys. Corp.*, 416 F. Supp. 2d 239, 250 (D. Mass. 2006)).

Here, at least some of the allegedly fraudulent statements are quintessential expressions of corporate optimism and subjective opinion that courts in this district have found to be immaterial. *See, e.g.*, *In re Cytyc Corp. Sec. Litig.*, 2005 WL 3801468, at *22 (D. Mass. Mar. 2, 2005) (finding statements about "momentum" and "consistent" growth non-actionable); *Orton v. Parametric Tech. Corp.*, 344 F. Supp. 2d 290, 301 (D. Mass. 2004) (finding statements "we are pleased with . . . [the] results" and "[the company is] position[ed] . . . for long-term growth" were "classic example[s] of non-actionable corporate puffery"); *In re Parametric Tech. Corp. Sec. Litig.*, 300 F. Supp. 2d 206, 217-18, 221 (D. Mass. 2001) (finding statements that company "expects more revenue growth" and "continue[s] to have confidence in the fundamental strength

of our business and our strong competitive position" were immaterial).[16] In particular, the following subjective, optimistic statements would not be considered material by a reasonable individual investor or by the market as a whole:

- "we think there's plenty of tailwind left" (Compl. ¶ 106);
- "our core business based on our existing suite of products is robust" (*Id.* ¶ 108);
- "products continue to do well" (*Id.*);
- "we believe that [Tecfidera] will continue to be a major business driver" (*Id.*);
- "we believe in the continued growth potential of the product in the U.S." (*Id.* ¶ 113);
- "we think Tecfidera is a terrific product that is going to perform very well in the market" (*Id.* ¶ 128);
- "certainly [Tecfidera is] our main driver here continuing to grow, continuing to do well" (*Id.* ¶ 131);
- "we believe that [Tecfidera] is a compelling treatment option for MS patients, and our long-term outlook for [Tecfidera] and for our entire MS portfolio, remains strong" (*Id.* ¶ 135);
- "we like the profile [of Tecfidera] and we think we can execute to continue growth" (*Id.* ¶ 143);
- "we'd be surprised if we don't see forward momentum from here" (*Id.* ¶ 145).

[16] *See also In re Apple Comput., Inc.*, 127 F. App'x 296, 304 (9th Cir. 2005) ("We have held the following similar statements to be non-actionable puffery: 'We're *doing well* and I think we have a great future'; . . . 'Old products are *doing very well*.'" (emphasis added)); *In re Ubiquiti Networks, Inc. Sec. Litig.*, 33 F. Supp. 3d 1107, 1133 (N.D. Cal. 2014) (holding that defendant's statement to analysts "those countries all *continue to do well* for us" was "puffing," in part, because he omitted any mention of "why, how, under what standard, or compared to what those markets were doing well" (emphasis added)).

In short, many of the alleged misrepresentations are immaterial expressions of corporate optimism or puffery, and are therefore not actionable.

3. Not Adequately Alleged to be False

As to the balance of the alleged misrepresentations and omissions, defendants contend that the complaint does not adequately allege that the statements were false or misleading when made. Plaintiffs counter by contending that the alleged statements created a "false impression that the PML death was having little or no negative impact on Tecfidera sales, and physicians[' prescribing behavior]." (Pl. Mem. 29).

There are at least three statements that, after drawing all reasonable inferences on behalf of plaintiffs, appear to be plausibly misleading or even false. All three statements occurred during the first quarter of 2015, were made by Kingsley, and concern Tecfidera's discontinuation rates:

- Kingsley on the January 29, 2015 earnings call: "Importantly, we have not noticed a meaningful change in [Tecfidera] discontinuation rates." (Compl. ¶ 113).
- Kingsley on the same earnings call: "[T]he lack of any meaningful change that we see—or we believe we're seeing—in the discon[tinuation] rate is encouraging, because it doesn't suggest there's such a change in the profile that people are anxious to pull patients out, but on the contrary." (*Id.* ¶ 117)
- Kingsley at the February 25, 2015 healthcare conference: "We have not seen any change in the discontinuation rate. There is a natural discontinuation rate for a product like Tecfidera in terms of tolerability and other things. You'd obviously get very concerned if you saw a spike in the discontinuation rate. No evidence of

> that. . . . [The discontinuation rate has] been consistent with—I mean, we look at it relative to the growth of the product. There's nothing that's a signal that says it's not consistent with historical averages." (*Id.* ¶ 128; Def. Ex. 14 at 5).

At least three facts contribute to a plausible inference that one or more of those statements was false or misleading. First, Tecfidera revenue for the first quarter of 2015 did not just experience slowing growth, it actually decreased $91 million, or 9.9 percent, from the fourth quarter of 2014. (Compl. ¶ 43). Second, at least one confidential witness stated that "very early in 2015" he witnessed "physicians . . . transferring patients off Tecfidera and onto different therapies." (*Id.* ¶ 61). Third, after the class period, during the second quarter 2015 earnings call on July 24, 2015, Biogen's executive vice president of research and development stated "[c]ertainly one of the dynamics that we've seen, that we didn't expect was a modest but not trivial increase in discontinuations in Tec[fidera] in the United States in particular." (*Id.* ¶ 153; Def. Ex. 23 at 13).[17]

Certainly, those are not the only inferences that can be drawn from Kingsley's statements. For example, the statements on January 29, 2015, were made only one month into the first quarter. Accordingly, the fact that Tecfidera produced lower revenue for the first quarter *as a whole* and Williams' acknowledgement *seven months later* that the company had seen a modest, but not trivial, increase in the discontinuation rate does not prove that the statements were false when made; neither does an allegation from a single confidential source stating that sometime in "early 2015" *some* physicians in *one* region of the country *began* transferring patients off Tecfidera. Nevertheless, two months into a quarter during which Tecfidera revenue

[17] The statements at issue concern the "discontinuation" rate, which is the rate at which physicians stop prescribing Tecfidera for their patients. It is only one of a number of factors affecting the growth rate for use of the product; the other principal factors appear to be "new starts" and "switches."

decreased 10 percent, Kingsley stated "we have not seen any change in the discontinuation rate." And during the very same conference, Kingsley stated "we've talked in the past we are getting about a third of new starts . . . and we're getting a nice portion of the switch pool as well." (Compl. ¶ 128). Therefore, because Kingsley's statements suggest that new starts and switches remained positive and consistent with historical numbers, even though Tecfidera revenue actually decreased, it is at least plausible that the three statements were false or misleading.

4. Conclusion

In summary, many of the alleged statements do not appear to be actionable under the PSLRA, whether considered separately or taken as a whole. However, drawing all reasonable inferences on behalf of plaintiffs, the complaint includes sufficient allegations to conclude that at least three of the alleged statements were material misrepresentations or omissions.

C. Allegations of Scienter

To be actionable under the PSLRA, a statement must be more than merely material and misleading; it also must have been made with the requisite scienter. *See ACA Fin.*, 512 F.3d at 58-59. "Scienter is 'a mental state embracing intent to deceive, manipulate, or defraud.'" *Id.* (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976)).

"A complaint will survive a motion to dismiss only if it states *with particularity* facts giving rise to a *strong inference* that defendants acted with a conscious intent to deceive or defraud investors by controlling or artificially affecting the price of securities[,] or acted with a high degree of recklessness." *Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 240 (citations and internal quotation marks omitted) (emphasis added); *accord ACA Fin.*, 512 F.3d at 58-59; *see also* 15 U.S.C. § 78u-4(b)(2). "It does not suffice that a reasonable factfinder plausibly could infer from the complaint's allegations the requisite state of mind." *Tellabs*, 551 U.S. at 314.

Instead, the court must "engage in a comparative evaluation" and weigh "competing inferences" to determine whether the inference of scienter is "cogent and compelling." *Id.* at 314, 324. A "'strong inference' of scienter 'must be more than merely plausible or reasonable—it must be cogent and *at least as compelling as any other opposing inference* of nonfraudulent intent.' In other words, where there are equally strong inferences for and against scienter, *Tellabs* now awards the draw to the plaintiff." *ACA Fin.*, 512 F.3d at 59 (citations omitted) (emphasis in original) (quoting *Tellabs*, 551 U.S. at 314).

"In this circuit, a plaintiff may satisfy the scienter requirement with a showing of either conscious intent to defraud or 'a high degree of recklessness.'" *Id.* at 58 (quoting *Aldridge*, 284 F.3d at 82); *accord Greebel*, 194 F.3d at 198-201. "Recklessness in this context means 'a highly unreasonable omission, involving not merely simple, or even inexcusable[] negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious the actor must have been aware of it.'" *Mississippi Pub. Emps. Ret. Sys. v. Boston Sci. Corp. II*, 649 F.3d 5, 20 (1st Cir. 2011) (quoting *SEC v. Fife*, 311 F.3d 1, 9-10 (1st Cir. 2002)); *see also Greebel*, 194 F.3d at 188 (noting that recklessness in this context "does not include ordinary negligence, but is closer to being a lesser form of intent"). "Even if plaintiffs wish to prove scienter by 'recklessness,' they still must allege with sufficient particularity, that defendants had full knowledge of the dangers of their course of action and chose not to disclose those dangers to investors." *Maldonado v. Dominguez*, 137 F.3d 1, 9 n.4 (1st Cir. 1998).[18] "Knowingly omitting material information is probative, although not determinative, of scienter." *Mississippi Pub.*

[18] It is also well-established that "[p]leading 'fraud by hindsight,' essentially making general allegations 'that defendants knew earlier what later turned out badly,' is not sufficient." *Ezra Charitable Trust v. Tyco Int'l, Ltd.*, 466 F.3d 1, 6 (1st Cir. 2006) (quoting *Gross v. Summa Four, Inc.*, 93 F.3d 987, 991 (1st Cir. 1996)).

Emps. Ret. Sys. I, 523 F.3d at 87; *see also Aldridge*, 284 F.3d at 83 ("[T]he fact that the defendants published statements when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence of scienter.").

Scienter "should be evaluated with reference to the complaint as a whole rather than to piecemeal allegations." *ACA Fin.*, 512 F.3d at 59; *see also Tellabs*, 551 U.S. at 310 ("[T]he inquiry . . . is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard."). "There is no set pattern of facts that will establish scienter; it is a case-by-case inquiry." *ACA Fin.*, 512 F.3d at 66. Compelling evidence of scienter most often includes "clear allegations of admissions, internal records or witnessed discussions" that suggest that defendants were "aware that they were withholding vital information or at least were warned by others that this was so" when they made the misleading statements. *In re Bos. Sci. Corp. Sec. Litig.*, 686 F.3d 21, 31 (1st Cir. 2012). In addition, courts have "considered many different types of evidence as relevant to show scienter," including

> insider trading . . . ; closeness in time of an allegedly fraudulent statement or omission and the later disclosure of inconsistent information; evidence of bribery by a top company official; existence of an ancillary lawsuit charging fraud by a company and the company's quick settlement of that suit; disregard of the most current factual information before making statements; disclosures of accrual basis in a way which could only be understood by a sophisticated person with a high degree of accounting skill; the personal interest of certain directors in not informing disinterested directors of impending sale of stock; and the self-interested motivation of defendants in the form of saving their salaries or jobs.

Greebel, 194 F.3d at 196 (citations omitted). In addition, various other "facts and circumstances indicating fraudulent intent—including those demonstrating motive and opportunity"—may also combine to satisfy the scienter requirement. *In re Cabletron Sys.*, 311 F.3d at 39. The "presence of [contemporaneous] insider trading can be used, in combination with other evidence, to

establish scienter." *Biogen IDEC Inc.*, 537 F.3d at 55. However, "[i]nsider trading cannot establish scienter on its own, but rather can only do so in combination with other evidence." *Mississippi Pub. Emps. Ret. Sys. II*, 649 F.3d at 29.

Here, plaintiffs' theory of scienter has two components. The first is that "ten credible and diverse former Biogen employees provide a compelling, corroborated description of the true crisis that unfolded at Biogen during the class period after the PML death was announced in October 2014." (Pl. Mem. 5). In other words, plaintiffs contend that the allegations of the confidential witnesses establish that defendants knew, or were at a minimum reckless in not knowing, about the real impact the PML death was having on Tecfidera, and that they intentionally or recklessly misled investors about that impact. The second component, referred to as "additional scienter allegations" in the complaint, includes allegations that defendants had both the opportunity to know the true state of Tecfidera sales and the motive to misrepresent them to investors. The complaint also alleges that Tecfidera's status as Biogen's most important product, or part of its "core operations," contributes to an inference of scienter.

Defendants' proposed inference is that Tecfidera sales growth began to slow in 2014—a fact that defendants disclosed both before and throughout the class period—and that the PML death—again, a risk that they disclosed—had a greater and longer-lasting impact on Tecfidera than they anticipated.

There is little doubt that the scienter allegations are plausible. That is not, however, the relevant question; rather, it is whether the allegations support a "strong inference" of scienter as the law requires. As set forth below, the allegations of the confidential witnesses are not sufficient to support a strong inference of scienter on their own, and the complaint's "additional scienter allegations" add little and are not enough to tip the balance. Accordingly, and for the

following reasons, the complaint's allegations are insufficient to support a strong inference of scienter.

1. Confidential Witness Allegations

The confidential witness allegations, although multiple and generally corroborative, are insufficient to support a strong inference of scienter.

First, those allegations are not specific enough to support a strong inference that defendants acted with intent to defraud or even with recklessness. *See In re Cabletron Sys.*, 311 F.3d at 30, 39 (concluding that confidential witness allegations about company's fraudulent inventory practices supported a strong inference of scienter because they "ma[de] adequate particularized allegations of large-scale fraudulent practices over time," and "specific descriptions of the precise means through which [the fraud] occurred"); *Coyne v. Metabolix, Inc.*, 943 F. Supp. 2d 259, 267, 271 (D. Mass. 2013) (concluding that confidential witness allegations were "both conclusory and too vague" and included "no specific facts capable of demonstrating that [d]efendants knew the information that [plaintiff] alleges contradicted their public statements"). Certainly "[t]he Court cannot construe the PSLRA's pleading requirement to mean that confidential witnesses, who are former employees of the [c]ompany, must recall all possible details from their former positions," nor are plaintiffs required to plead evidence. *Collier v. ModusLink Glob. Sols., Inc.*, 9 F. Supp. 3d 61, 73 (D. Mass. 2014). Nonetheless, the PSLRA requires that the confidential witnesses allege "with *particularity* facts giving rise to a *strong* inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A) (emphasis added).

The analysis begins with the allegations from the seven ABMs (CW1, CWs 3 through 7, and CW9) concerning Tecfidera sales. According to the ABMs, the following occurred around

late 2014 and early 2015: sales "dropped steeply and immediately"; there was a "large drop in new prescription sales"; there was a "sharp decline" in sales; "sales dropped dramatically"; there was "a large drop in new prescription sales"; "sales dropped appreciably"; there was a "big slowdown" in market expansion; there was a "serious downturn" in "start forms"; "new prescriptions significantly slowed down"; and sales "took a hit." (Compl. ¶¶ 56, 58, 60-65).

Notably absent from those allegations are any *specific* facts about the sales, such as a measurement of the sales decline, why sales were declining, whether the decline was due to lower new starts and switches or higher discontinuations, or how the sales decline affected the company's financial guidance. *See Coyne*, 943 F. Supp. 2d at 266-67 (concluding that "vague (and largely conclusory) allegations of struggling sales, problems with production, and difficulty retaining repeat clients" were insufficient to demonstrate that company was "*incapable* of meeting its predicted target"). Furthermore, the complaint does not allege that any of the seven ABMs—most of whom were regional sales employees five levels removed from any of the defendants—or any of the other confidential witnesses ever spoke with one of the defendants. *See Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 245 (noting that the confidential witnesses were not in "senior management positions, and they appear to have had relatively little ongoing contact with senior management").[19]

Plaintiffs contend that defendants' objection to the vagueness of the confidential witness allegations is "myopic," and that requiring them to allege more would require them to plead evidence of fraud. But particularized facts about the Tecfidera sales decline (and more specifically, discontinuations) and whether defendants recklessly or intentionally misled investors about such a decline are necessary here, where defendants specifically warned

[19] There is likewise no allegation that any of the CWs witnessed a fraudulent act, or created or read a false document.

investors about slowing Tecfidera growth before and throughout the class period. On October 22, 2014, even before the PML death had any impact on Tecfidera sales, Kingsley warned the market about Tecfidera's slowing growth, stating "we have always expected Tecfidera's growth rate would moderate over time. I think we are seeing a natural case of that." (Def. Ex. 7 at 8). On January 29, 2015, shortly after the beginning of the class period and during the very same call that Biogen announced record annual and quarterly revenue for Tecfidera (and the company as a whole), Kingsley stated that he was seeing slowing Tecfidera sales due, in part, to the PML death:

> As you may have seen through IMS, we observed moderating new starts for Tecfidera, including a decline in the overall market switch rate, *the U.S. label update in December*, and the recent launch of Plegridy, which is capturing some interferon switches that otherwise may have gone to Tecfidera.
>
> Importantly, we have not noticed a meaningful change in Tecfidera discontinuation rates . . . .

(Def. Ex. 12 at 5) (emphasis added). On February 25, 2015—the same day that the complaint alleges he intentionally or recklessly misled investors about Tecfidera's discontinuation rates—Kingsley again noted the "slowing of the growth rate," told investors that the PML death was a "meaningful event that [Biogen] ha[s] to manage through," and stated that he thought Tecfidera was "resilient" in the face of "hesitancy" among physicians. (Def. Ex. 14 at 4).

In other words, absent more particularized details and stripped of their generalities, the confidential witness allegations about Tecfidera sales are not clearly inconsistent with what defendants were publicly disclosing to the market. *See New Jersey Pension & Annuity Funds*, 537 F.3d at 52 (concluding that a confidential source's vague allegation that patients being treated with defendants' pharmaceutical suffered "several" infections during trial was not inconsistent with what defendants publicly disclosed and therefore did not "contribute anything

additional to plaintiffs' case"); *Automotive Indus. Pension Trust Fund v. Textron Inc.*, 682 F.3d 34, 40 (1st Cir. 2012) ("If [defendant] knowingly understated the number of cancellations . . . this would be classic evidence of scienter. But . . . on the crucial question of when cancellations began piling up, [defendant's] statement and the confidential witness' description of cancellations increasing 'suddenly' in 'late summer' are not in conflict." (citation and internal quotation marks omitted)). Accordingly, the relatively vague statements of the confidential witnesses, absent more particularized details, lend support to an inference of scienter, but not a strong one.

The allegations about a March 2015 national sales meeting and Biogen's lowering of employees' sales goals likewise add little to the inference of scienter. The complaint alleges that CW1 and CW3 attended a national sales meeting in March 2015 (after Kingsley's three statements about the discontinuation rates, and well after the company's January projections). According to the allegations, unidentified "senior Biogen leaders" at the meeting acknowledged that the PML death "definitely was impacting sales," some unidentified person described the death as a "market event," and some unidentified person stated that "sales [presumably of Tecfidera] would need to pick up again if [Biogen] was going to meet expected 14-16% revenue growth." (Compl. ¶¶ 59-60).

Missing from those allegations are any details about the magnitude of the "impact" on sales, a change in the discontinuation rate, who made the statements, or even whether any of the defendants attended the meeting. The allegations also support the inference that Tecfidera growth was slowing due to a number of factors, including the PML death, as defendants disclosed. CW1 and CW5 allege that Biogen lowered sales goals for ABMs around January 2015, and that a Biogen vice president sent an e-mail stating that the adjustment was due to

"lower guidance due to unforeseen market events." (Compl. ¶¶ 74-75). A "concealed change in company policy might, depending on the circumstances, assist an inference of scienter." *Automotive Indus. Pension Trust Fund*, 682 F.3d at 39. However, there are no allegations that defendants took any steps to conceal the change, and again, the allegations do not include particularized details about the magnitude of the change or defendants' involvement in it. Biogen's efforts to assist its sales employees to reach compensation goals while also warning the market about slowing Tecfidera growth do not warrant a strong inference of fraud.

Finally, the complaint alleges that CW2 attended a November 2014 Biogen "town hall" meeting led by Scangos. Notably, the allegation as to the town hall meeting is the only one that directly involves one of the defendants. According to CW2, Scangos's presentation stated that "the overall sense of the trajectory [at Biogen] was changing," and another presentation addressed "potential organizational changes as a result of the PML death." (Compl. ¶ 57). "It was CW2's understanding that the organizational changes stemmed from executive management's expectation that the PML death would have 'an impact on performance.'" (*Id.*). Again, those allegations are vague and otherwise consistent with competing inferences. For example, CW2 does not explain what the potential changes were, any details about how Biogen's "trajectory" was changing, how he came to the "understanding" that the changes were due to executive management's "expectation" about sales, or most importantly, what Scangos said about the alleged "impact." Even viewing CW2's nebulous allegations in light of the entire complaint, they require the Court to make several assumptions to piece together an inference of fraudulent intent or recklessness, let alone a compelling one.[20]

[20] The complaint's allegations as to CW10 and CW8 add little to the mix. CW10 was an executive assistant for Sundaram, the "program director of Tecfidera" who allegedly met frequently with Kingsley and Scangos. (Compl. ¶¶ 68-70). Although CW10 alleges that various executives and sales teams met to discuss Tecfidera sales and that Biogen representatives spoke with physicians, there is no detail about the content of those discussions.

Moreover, those allegations are consistent with the competing inference of a lack of scienter. Biogen had experienced meteoric revenue growth in 2014, and in November 2014 it was only weeks away from announcing 232 percent annual revenue growth for Tecfidera. Nevertheless, the "trajectory" of Tecfidera's growth was changing, as the company disclosed beginning in October 2014. (*See* Def. Ex. 7 at 8). Kingsley, in response to question about moderating Tecfidera growth in the third quarter of 2014, stated: "As always[,] a little probably difficult to predict exactly, but look, we have always expected Tecfidera's growth rate would moderate over time. I think we are seeing a natural case of that." Also, during the very same January 2015 call in which Biogen announced that annual Tecfidera revenue had more than doubled, Kingsley explicitly acknowledged that the PML announcement was having an "impact on performance." (*See* Def. Ex. 12 at 5) ("We believe several factors have *impacted* the recent performance of Tecfidera, including a decline in the overall market switch rate, the US label update in December . . . ." (emphasis added)). He also addressed Biogen's sales approach after the PML announcement, an approach that could be reasonably inferred to mean "organizational changes":

> I think the *educational initiatives* are underway, which is, we have sales forces out, talking to a broad set of physicians. Our medical team is providing support where there are requests. So I think we are [executing on this]—educating people to the label and what the label says. And answering those questions.

(Def. Ex. 12 at 13) (emphasis added).

In short, the various allegations of the confidential witnesses, taken as a whole, support a

(*Id.*). Indeed, the only allegation CW10 does add is that Sundaram "knew that the label change would immediately lead to lost sales." (*Id.* ¶ 70). The complaint does not allege how CW10 *knew* that Sundaram *knew* that fact; anything Sundaram allegedly said; any detail on the magnitude of lost sales; or whether Sundaram's apparent knowledge was shared by defendants. CW8 was Biogen's senior director of commercial operations from August 2014 to November 2015. He stated that 2015 was "difficult" for Tecfidera and that sales were a concern since the PML death. (*Id.* ¶ 66). Those allegations are not surprising, given that Biogen began warning the market about slowing sales before the class period even started.

plausible inference of scienter to some degree. However, without more, they are not sufficiently particularized to support a strong inference of scienter, as the law requires, and they are consistent with the competing non-fraudulent inferences.

2. Additional Scienter Allegations

The complaint's "additional" scienter allegations add little, if anything, to the confidential witness allegations. The complaint alleges that defendants had both the motive and opportunity to misrepresent Tecfidera's growth projections. However, some of the allegations make little sense in the factual context of Biogen's purported fraud, and they are otherwise too generic to support an inference of scienter. "'[C]atch-all allegations' which merely assert motive and opportunity, without something more, fail to satisfy the PSLRA." *In re Cabletron Sys.*, 311 F.3d at 39 (quoting *Greebel*, 194 F.3d at 197). Instead, motive and opportunity allegations must state "more than the usual concern by executives to improve financial results." *Id.*

For example, plaintiffs contend that "Scangos and Clancy *did* have motive based on compensation that included stock awards and bonus targets tied to revenue growth." (Pl. Mem. 12). That allegation does not make sense in this context. The complaint does not allege that Biogen's revenue *reporting* was false or misleading in any way. Instead, the complaint alleges that Biogen's future revenue *projections* were misleading. It is difficult to imagine why defendants would have the motive to overstate *projected* revenue growth based on the fact that they had bonuses tied to *actual* revenue growth.

It is also notable that the complaint is bereft of insider-trading allegations. While plaintiffs' counterargument—that insider trading can add to an inference of scienter but not detract from an otherwise strong inference—is perhaps technically correct, *see Aldridge*, 284 F.3d at 84, that is not the end of the analysis. The Court must read the complaint as a whole and

weigh competing inferences. Here, the lack of insider trading contributes to defendants' proposed inference that they simply underestimated the effect that the PML death would have on sales. Indeed, the individual defendants' holdings of Biogen stock actually *increased* during the class period according to the publicly-filed SEC Forms 4. (*See* Def. Ex. 26-28).[21] That fact negates an inference that defendants had a motive to artificially inflate Biogen's stock price. *See Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 246 ("[Defendant] *increased* his holdings of [company] stock by 9.2% during the class period, which negates any inference that he had a motive to artificially inflate [the company's] stock during that period."); *accord ACA Fin.*, 512 F.3d at 66-67 (declining to find a strong inference of scienter in part because defendants would not have been personally enriched by defrauding investors).[22]

Furthermore, the Court must weigh the fact that defendants themselves suffered investment losses based on the decline in Biogen's stock price. *See Maldonado*, 137 F.3d at 12 n.9 (noting the fact that defendants "invested and lost one and a half million dollars of *their own money* . . . undermine[d] any inference of scienter"). Here, based on Scangos's holdings of

[21] Scangos acquired 23,105 Biogen shares during the class period (net of sales and vested shares withheld); Clancy acquired 6,802 Biogen shares during the class period (net of vested shares withheld); and Kingsley acquired 4,621 Biogen shares during the class period (net of vested shares withheld). (Def. Ex. 26-28). Notably, neither Clancy nor Kingsley sold any Biogen shares during the class period, aside from shares withheld at the time of vesting to pay for tax liabilities. Plaintiffs contend that the Court should distinguish between "active" stock purchases and "passive" vesting of previously awarded shares, but they have not cited a case for that proposition.

[22] The complaint's allegations about Biogen's repurchase program are somewhat puzzling. The complaint alleges that "Biogen's Board of Directors voted to authorize a $5 billion share repurchase program in May 2015, two months before the full disclosure of the truth regarding Tecfidera's performance following the PML incident." (Compl. ¶ 171). Plaintiffs contend that "[t]his raises an inference that [d]efendants knew their misstatements and omissions would be revealed, and adopted the program to prop up its stock price." (Pl. Mem. 12) (citing *In re Countrywide Fin. Corp. Sec. Litig.*, 588 F. Supp. 2d 1132, 1187 n.67 (C.D. Cal. 2008). But the share repurchase program, if anything, actually negates an inference of scienter. It would make little sense for defendants to initiate a repurchase program if they knew Biogen's stock price was artificially inflated by their fraudulent misrepresentations. Plaintiffs fail to mention that in *Countrywide*, the court found that the repurchase program added to an inference of scienter *only* because the individual defendants used it to prop up the stock price while *they sold their own shares*. *See* 588 F. Supp. 2d at 1188 ("Again, as insiders were selling, Countrywide was buying . . . . The [complaint] creates a strong inference that Countrywide's explanation for its stock repurchase plan was economically suspect."). Here, not only did defendants fail to sell their shares, their holdings of Biogen stock actually increased during the class period.

41,090 shares, Clancy's 22,257 shares, and Kingsley's 8,132 shares, they combined to lose more than $6 million on July 24, 2015, when the stock price dropped $85. (*See* Def. Ex. 26-28).[23]

The complaint further alleges that defendants must have known that Biogen's Tecfidera revenue guidance was wrong due to their positions and access to "prescription and sales information." (Compl. ¶¶ 167, 173-75). Without more specific allegations, general and conclusory assertions that "headquarters knew about it" when a prescription was sold and that "headquarters would have had up to date insight into new prescription rates" provide little evidence to support an inference of scienter. (*Id.* ¶¶ 72, 73); *see Orton*, 344 F. Supp. 2d at 306 ("Nor does a vague assertion that a defendant must have known about the fraud by virtue of his position of authority suffice to prove a strong inference of scienter."); *Guerra v. Teradyne Inc.*, 2004 WL 1467065, at *25 (D. Mass. Jan. 16, 2004) (noting that it is "well established that merely stating the existence of efficient internal reporting systems in a conclusory fashion will not do much to increase the particularity of a securities fraud pleading," and rejecting such allegations in part because the complaint "otherwise failed to identify any specific [internal] report itself, the information in the reports they deem significant, or how such information rendered the representations at issue misleading").

Finally, the complaint's "core operations" allegations fall short of adding sufficient weight for the complaint to plead a strong inference of scienter. The complaint alleges that because Tecfidera was Biogen's main revenue source during the class period, accounting for 33.7% of total company revenue, defendants knew or were reckless in not knowing that their statements about Tecfidera were misleading. (Compl. ¶¶ 43, 68-75, 159-65). Certainly, under *Tellabs*, the "core operations" allegations and Tecfidera's importance to Biogen must be taken

[23] Of course, this decline must be viewed in light of defendants' total compensation. Scangos earned more than $18 million, and Clancy more than $4 million, in 2014. (Compl. ¶ 170).

into account as part of the Court's assessment of the complaint's scienter allegations. However, courts have been hesitant to apply significant weight to "core operations" allegations without other significant evidence of a defendant's intent or recklessness, or a "plus factor." *See In re A123 Sys., Inc. Sec. Litig.*, 930 F. Supp. 2d 278, 285 (D. Mass. 2013) ("Plaintiffs cite [*Crowell v. Ionics, Inc.*, 343 F. Supp. 2d 1, 19 (D. Mass. 2004)] for the proposition that 'facts critical to a business's core operations or an important transaction generally are so apparent that their knowledge may be attributed to the company and its officers.' *Crowell*, . . . [however,] involved allegations of the improper booking and accounting of fraudulent sales, buttressed by a 'plus factor'—an e-mail pointing to the company's vice president as the author of the scheme."); *see also Lenartz v. American Superconductor Corp.*, 879 F. Supp. 2d 167, 183 n.9 (D. Mass. 2012) (finding the core operations theory inapplicable in accounting fraud case because the facts were "less clear" than the "particularized facts" of *Crowell*). Here, there is no "smoking gun" e-mail or "plus factor" as in *Crowell*.[24]

In sum, the complaint's "additional" allegations of motive, opportunity, and "core product," taken as a whole, do not make the complaint's otherwise plausible inference of scienter strong enough to satisfy the PSLRA.

3. Opposing Inferences

Based on the complaint as a whole, plaintiffs' asserted inference of scienter may be plausible, but it is not strong, cogent, or compelling. Moreover, the Court "must weigh 'not only inferences urged by the plaintiff . . . but also competing inferences rationally drawn from the

[24] It appears that the First Circuit has not yet directly addressed the proper weight to give "core operations" allegations, and even courts in this district that have applied it have not done so unless the product is "central to [the company's] continued survival as a business entity." *See Lenartz*, 879 F. Supp. 2d at 183 n.9 (finding core operations allegations unpersuasive even though customer accounted for over 70 percent of company's revenue). Here, Tecfidera was certainly important to Biogen and probably the company's most important product, but even plaintiffs do not contend that it was central to the company's "continued survival as a business entity."

facts alleged.'" *New Jersey Carpenters Pension*, 537 F.3d at 45 (quoting *Tellabs*, 551 U.S. at 314). There are at least three facts that further weaken the inference of scienter here.

Most obviously, defendants were cautious in projecting Tecfidera's growth, and they repeatedly warned investors about the downside risks, including moderating growth and the PML label change. As the First Circuit has consistently noted, "'attempts to provide investors with warnings of risks generally weaken the inference of scienter.'" *Waters Corp.*, 632 F.3d at 760 (quoting *Ezra Charitable Trust*, 466 F.3d at 8); *see Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 243 (concluding that plaintiffs' contention that defendants made statements about pharmaceutical revenues with reckless disregard as to whether investors would be deceived was "undercut by the fact that [the defendant company] *explicitly* warned investors" that an FDA enforcement action "'could result in reduced demand for our products and would have a material adverse effect on our operations and prospects'"); *Genzyme Corp.*, 754 F.3d at 42-43 (noting that a corporation's informative disclosures "undercut any inference of fraudulent intent on the part of defendants").

Both plaintiffs' brief and the complaint gloss over Biogen's disclosures in an effort to make the case for scienter more compelling, but the transcripts reveal a more complete picture. For example, during a call on October 22, 2014, Biogen announced the PML death and stated that it "reported the case to the regulatory authorities" and that it would "work with them to confirm that the language on [Tecfidera's] label provides patients and their physicians appropriate information regarding lymphopenia." (Compl. ¶ 48; Def. Ex. 7 at 3). During the same call, Kingsley responded to an analyst's question (about third-quarter Tecfidera growth being the lowest of the previous five quarters) by noting that growth was moderating and difficult to predict. (Compl. ¶ 48; Def. Ex. 7 at 7-8) ("As always a little probably difficult to

predict exactly, but look, we have always expected Tecfidera's growth rate would moderate over time. I think we are seeing a natural case of that.").[25]

Once the class period began, Clancy stated on December 2, 2014, that investors should be "mindful" of Tecfidera's discontinuation rates, which were in the "teens" and higher than the company would have hoped for an oral MS therapy. (Def. Ex. 8 at 2-4).[26] On January 29, 2016, after announcing record quarterly revenue for Tecfidera, Kingsley stated that the company had observed "moderating new starts for Tecfidera in the fourth quarter" and that it "believe[d] several factors have impacted the recent performance of Tecfidera, including a decline in the overall market switch rate, [and] the U.S. label update in December . . . ." (Compl. ¶ 113; Def. Ex. 12 at 5). He also stated that the reasons for slowing growth were "[a]ctually hard to piece apart." (Def. Ex. 12 at 11-13). In the same breath that he stated that he did not "believe" he was seeing a "meaningful change" in Tecfidera's discontinuation rate, he was again cautious: "Look—I think that, naturally, in a case like this, as people are processing the new label, you'll see softness in switch rate for a period of time." (*Id.*).

In February 2016, Kingsley again noted the effect that the PML death was having on Tecfidera, despite the drug's resilience:

> Fourth quarter, we had the report of 1 PML incident and I think we talked about this in earnings call and toward the end of the year which is that's a *meaningful event that you have to manage through*, right? *There's a lot of communication that has to happen to physicians*. You would expect to see *some hesitancy among some set of physicians before you get to them to have a conversation*. But that would—the product's been quite resilient, I think, is our view in light of that. 2015, we think it's still a meaningful growth driver.

[25] Notably, the complaint alleges that "[a]nalysts accepted defendants' *statements that the PML death would not have a material impact on Tecfidera*." (Compl. ¶ 50) (emphasis added). None of the defendants made any such statements during the call.

[26] On the same call, Clancy stated that Biogen "expect[ed] a label change" due to the PML death. (Def. Ex. 8 at 2-4).

(Compl. ¶ 128; Def. Ex. 10 at 4-5) (emphasis added). When directly asked to predict whether "a lot of the [] PML noise or news" had come out in the fourth quarter of 2015 after the December label change, or whether it would carry over into the first quarter, Kingsley was again, at the very least, cautious:

> Yes, so the information certainly got out in the fourth quarter. Looking at analogous situations with other products, *we typically think you might have a 2, 3 month time frame where this presses*, but that's looking at analogies. So *impossible to predict with great accuracy*.

(Compl. ¶ 128; Def. Ex. 10 at 4-5) (emphasis added).

During the first-quarter-earnings call in April 2015, Scangos noted that "Tecfidera had a more challenging quarter, due to a number of issues, including . . . the single PML case reported last year." (Def. Ex. 17 at 3). Kingsley again reminded investors about the PML death when he stated, "We believe [moderation in growth rates] is occurring as expected, but also believe that the [Tecfidera] safety event in October further dampened market growth and switch rates in Q1." (Def. Ex. 17 at 4-5). Finally, Clancy warned the market that "[i]f the U.S. [Tecfidera] trajectory does not improve, we may come in at the lower end of our previously provided revenue growth [range of 14 to 16 percent]." (Compl. ¶ 135; Def. Ex. 17 at 5-6). In May 2015, Clancy stated that the "unfavorable impact" that the PML death had on physicians' attitudes toward Tecfidera had "stabilized" but that it "hasn't turned around as quick as we had wanted it to turn around." (Compl. ¶ 139; Def. Ex. 18 at 2-3).

Other factors appear to support the inference that defendants, at worst, negligently overestimated Tecfidera's short-term revenue growth after the PML death. After Biogen announced record quarterly revenue of $916 million in the fourth quarter of 2014, Tecfidera revenue dropped in the first quarter and demonstrated tepid growth in the second quarter due, in part, to the PML death. Notably however, after the class period, Tecfidera revenue rebounded to

$937 million in the third quarter and $993 million in the fourth quarter of 2015, contributing to annual growth rates of 25.1 percent and 10.9 percent for Tecfidera and Biogen, respectively. That demonstrates the "meaningful" but "moderating" growth that defendants expected. Moreover, the complaint contains no allegation that defendants hid or otherwise delayed in announcing the PML death to investors, or the subsequent label change. *See Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 243 (noting that medical company defendant "did not withhold information about the FDA's concerns once the FDA issued a Warning Letter" and "did not promise a positive resolution of the matter").

In short, "[t]hese are not the actions of a company bent on deceiving investors as to their future earnings prospects." *See id.* Defendants' warnings about the PML death fall far short of reckless conduct and do not support an inference of scienter. Rather, they support the inference that defendants were, at worst, overly optimistic in attempting to predict the PML death's effect on revenues.[27]

4. Conclusion

Considered as a whole, the complaint presents allegations of scienter that are perhaps plausible, but not "cogent and compelling." *Tellabs*, 551 U.S. at 324; *see also ACA Fin.*, 512 F.3d at 59 (noting that scienter "should be evaluated with reference to the complaint as a whole rather than to piecemeal allegations"). Again, the allegations from confidential sources—none of whom personally spoke to defendants or witnessed any overtly fraudulent behavior—contribute somewhat to plaintiffs' asserted inference of scienter. However, they are too vague and

[27] As Kingsley warned investors, that effect was inherently difficult to predict. (*See* Def. Ex. 7 at 7-8) (Kingsley: "As always a little probably *difficult to predict exactly*, but look, we have always expected Tecfidera's growth rate would moderate over time. I think we are seeing a natural case of that." (emphasis added)); (*See* Def. Ex. 10 at 4-5) (Kingsley: "[S]o the [PML death] information certainly got out in the fourth quarter. Looking at analogous situations with other products, we typically think you might have a 2, 3 month time frame where this presses, but that's looking at analogies. So *impossible to predict with great accuracy*." (emphasis added)).

conclusory to create a strong inference of recklessness or intent. Indeed, the allegations concerning physicians' discomfort after the PML death and declining Tecfidera sales are at least partly consistent with defendants' repeated public disclosures. Furthermore, the complaint's "additional" motive and core-product allegations provide very little support to an inference of scienter. Without more, plaintiffs' circumstantial case of scienter is not strong or compelling.

In sum, even after drawing all reasonable inferences on behalf of plaintiffs, the most compelling inference to be drawn from the complaint as a whole is that defendants were unduly optimistic—at worst, negligently so—in predicting how quickly Tecfidera sales would recover from the PML announcement. "Still, 'allegations of corporate mismanagement are not actionable under Rule 10b-5. Nor are allegations of mere negligence.'" *Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 246 (quoting *Waters Corp.*, 632 F.3d at 760) (alteration omitted). Without evidence sufficient to support a strong inference of intent, or at least recklessness, defendants' failure to predict the future does not support a claim for securities fraud; accordingly, under the heightened pleading standard of the PSLRA, Count One will be dismissed.

D. Count Two: Scheme Liability under Rules 10b-5(a),(c)

Count Two of the complaint asserts a claim against defendants for "scheme" liability under Rules 10b-5(a) and 10b-5(c). However, plaintiffs have conceded that claim in their opposition brief. (Pl. Mem. 30 n.24) ("Plaintiff[s] do[] not contest the claim for scheme liability."). Accordingly, Count Two will be dismissed.

E. Count Three: Section 20(a) Liability

Count Three of the complaint asserts a claim against the individual defendants under Section 20(a) of the Exchange Act, which imposes joint and several liability on persons in

control of entities that violate securities laws. 15 U.S.C. § 78t. However, violations of Section 20(a) depend on an underlying violation of the Exchange Act. 15 U.S.C. § 78t-1(a); *see Waters Corp.*, 632 F.3d at 762 ("Because the plaintiff's Section 20(a) claim was derivative of the Rule 10b-5 claim, it was properly dismissed as well."); *ACA Fin.*, 512 F.3d at 67-68. Because the complaint fails to state a claim for an underlying violation of the Exchange Act, Count Three will be dismissed.

F. Leave to Amend

Plaintiffs have not formally requested leave to amend the amended complaint. Instead, on the final page of their thirty-page opposition to defendants' motion to dismiss, plaintiffs contend that "leave to amend should be permitted if defendants' motion is granted." (Pl. Mem. 30). Plaintiffs do not state that they have discovered, or could discover, new evidence to suggest that amendment would not be futile; rather, they cite Rule 15(a) and state that "[l]eave to amend is to be 'freely given.'" (*Id.*) (quoting Fed. R. Civ. P. 15(a)).

The original complaint in this case was filed on August 18, 2015, and GBR was appointed the lead plaintiff in November 2015. During the November 17, 2015 status conference, the Court allowed plaintiffs' request for an additional sixty days to file an amended complaint, albeit with some reservation about the schedule of the case. The Court, however, warned plaintiffs' counsel "I'm sure you know . . . because this is often the ball game in [securities fraud] cases, if you have factual allegations, they should be in the complaint. In other words, don't hold something back, wait and see if I grant the motion to dismiss or not and then seek to amend the complaint. If you've got something, put it in." (Docket No. 51 at 7:11-17). The amended complaint was filed on January 19, 2016. Accordingly, plaintiffs, and the three law firms listed as their counsel, had more than five additional months between the filing of the

initial complaint and the amended complaint to thoroughly investigate their claims—an investigation that should have been completed, at least predominantly, before filing the *original* complaint. Moreover, plaintiffs had the opportunity to request leave to amend the amended complaint after defendants filed their motion to dismiss, as well as after the motion hearing, during which the Court expressed skepticism about the complaint's ability to survive the PSLRA's rigorous scienter requirement.

As the First Circuit succinctly stated in denying a request for leave to amend in another securities fraud class action:

> On a hopeless quest, plaintiffs argue we should remand to allow them to amend the complaint. No proper request was made to the district court, only a mention in a footnote in their opposition to dismissal.
>
> In any event, it is far too late; plaintiffs were put on notice of the deficiencies in the complaint by the motion to dismiss. If they had something relevant to add, they should have moved to add it then. And even now there is no suggestion that amendment would be anything other than futile. *We wish to discourage this practice of seeking leave to amend after the case has been dismissed.*

Fire and Police Pension Ass'n of Colo., 778 F.3d at 247 (emphasis added) (citations omitted); *see also ACA Fin.*, 512 F.3d at 57 (rejecting plaintiffs' argument that district court erred in denying leave to amend because "[p]laintiffs took no action to add new allegations" in response to defendants' motion to dismiss "even though they knew what they would add if they amended," and noting that allowing such a practice would "lead to delays, inefficiencies, and wasted work").

Accordingly, the Court will not grant plaintiffs' informal request for leave to amend after ruling on defendants' motion to dismiss.

V. Conclusion

For the foregoing reasons, defendants' motion to dismiss is GRANTED.

So Ordered.

/s/ F. Dennis Saylor
F. Dennis Saylor IV
Dated: June 23, 2016 United States District Judge